COLORADO
Department of Health Care Policy & Financing

Health First COLORADO
Colorado's Medicaid Program

Colorado Department of Health Care Policy and Financing
Preferred Drug List (PDL)
Effective January 1, 2021

PA Forms: Available online at https://www.colorado.gov/hcpf/pharmacy-resources
PA Requests: Colorado Pharmacy Call Center Phone Number: 800-424-5725 | Colorado Pharmacy Call Center Fax Number: 800-424-5881
The PDL applies to Medicaid fee-for-service members. It does not apply to members enrolled in Rocky Mountain Health HMO or Denver Health Medicaid Choice.

Initiation of pharmaceutical product subject to Prior Authorization:
Please note that starting the requested drug, including a non-preferred drug, prior to a PA request being reviewed and approved, through either inpatient use, by using office "samples", or by any other means, does not necessitate Medicaid approval of the PA request.

Health First Colorado, at 25.5-5-501, requires the generic of a brand name drug be prescribed if the generic is therapeutically equivalent to the brand name drug. Exceptions to this rule are: 1) If the brand name drug is more cost effective than the generic as determined by the Department, 2) If the patient has been stabilized on a brand name drug and the prescriber believes that transition to a generic would disrupt care, and 3) If the drug is being used for treatment of mental illness, cancer, epilepsy, or human immunodeficient virus and acquired immune deficiency syndrome.

Brand Name Required = BNR, Prior Authorization = PA, AutoPA = authorization can be automated at the point of sale transaction if criteria is met
Preferred drug list applies only to prescription (RX) products, unless specified

<table>
<tr><th>Preferred Agents</th><th>Non-preferred Agents</th><th>Prior Authorization Criteria
(All Non-preferred products will be approved for one year unless otherwise stated.)</th></tr>
<tr><td colspan="3"><h2>I. Analgesics</h2></td></tr>
<tr><td colspan="3">Therapeutic Drug Class: NON-OPIOID ANALGESIA AGENTS - Oral - Effective 7/1/2020</td></tr>
<tr><td>No PA Required

Duloxetine capsule (generic Cymbalta)

Gabapentin capsule, tablet, solution

Pregabalin capsule</td><td>PA Required

CYMBALTA (duloxetine)

DRIZALMA (duloxetine DR) sprinkle capsules

Duloxetine capsule (generic Irenka)

GRALISE (gabapentin ER)</td><td>Non-preferred oral non-opioid analgesic agents may be approved if member meets all of the following criteria:
● Member has trialed and failed duloxetine (20mg, 30mg, or 60mg) AND has trialed and failed gabapentin OR pregabalin capsule (Failure is defined as lack of efficacy with 8-week trial, allergy, intolerable side effects, or significant drug-drug interaction)

Prior authorization will be required for Lyrica (pregabalin) capsule dosages > 600mg per day (maximum of 3 capsules daily) and gabapentin dosages > 3600mg per day.</td></tr>
</table>

	LYRICA (pregabalin) capsule, solution, CR tablet NEURONTIN (gabapentin) capsule, tablet, solution Pregabalin solution SAVELLA (milnacipran) tablet	
Therapeutic Drug Class: **NON-OPIOID ANALGESIA AGENTS - Topical** - *Effective 7/1/2020*		
No PA Required Lidocaine patch	**PA Required** LIDODERM (lidocaine) patch ZTLIDO (lidocaine) topical system	Non-preferred topical products require a trial/failure with an adequate 8-week trial of gabapentin AND pregabalin AND duloxetine AND lidocaine patch. Failure is defined as lack of efficacy with an 8-week trial, allergy, intolerable side effects, or significant drug-drug interaction. Prior authorization will be required for lidocaine patch quantities exceeding 90 patches per 30 days (maximum of 3 patches daily).
Therapeutic Drug Class: **NON-STEROIDAL ANTI-INFLAMMATORIES (NSAIDS) - Oral** - *Effective 1/1/2021*		
No PA Required Celecoxib capsule Diclofenac potassium tablet Diclofenac sodium EC/DR tablet Ibuprofen suspension, tablet (RX) Indomethacin capsule, ER capsule Ketorolac tablet** Meloxicam tablet Nabumetone tablet Naproxen EC, DR/ER, suspension, tablet (RX) Sulindac tablet	**PA Required** ANAPROX DS (naproxen sodium) tablet ARTHROTEC (diclofenac sodium/ misoprostol) tablet CELEBREX (celecoxib) capsule DAYPRO (oxaprozin) caplet Diclofenac sodium ER tablets Diclofenac sodium/misoprostol tablet Diflunisal tablet DUEXIS (ibuprofen/famotidine) tablet Etodolac capsule, IR and ER tablet FELDENE (piroxicam) capsule Fenoprofen capsule, tablet Flurbiprofen tablet	**DUEXIS (ibuprofen/famotidine)** or **VIMOVO (naproxen/esomeprazole)** may be approved if the member meets the following criteria: • Trial and failure‡ of all preferred NSAIDs at maximally tolerated doses **AND** • Trial and failure‡ of three preferred proton pump inhibitors in combination with NSAID within the last 6 months **AND** • Have a documented history of gastrointestinal bleeding All other non-preferred oral agents may be approved following trial and failure‡ of four preferred agents. ‡Failure is defined as lack of efficacy, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interactions. **Ketorolac tablets quantity limitations: 5 day supply per 30 days and 20 tablets per 30 days

	INDOCIN (indomethacin) susp Ketoprofen IR, ER capsule Meclofenamate capsule Mefenamic acid capsule MOBIC (meloxicam) tablet NALFON (fenoprofen) capsule, tablet NAPRELAN (naproxen CR) tablet Naproxen sodium CR, ER, IR tablet Naproxen/esomeprazole DR tablet Oxaprozin tablet Piroxicam capsule QMIIZ (meloxicam) ODT TIVORBEX (indomethacin) capsule Tolmetin tablet, capsule VIMOVO (naproxen/esomeprazole) DR tablet VIVLODEX (meloxicam) capsule ZIPSOR (diclofenac) capsule ZORVOLEX (diclofenac) capsule	
Therapeutic Drug Class: **NON-STEROIDAL ANTI-INFLAMMATORIES (NSAIDS) - Non-Oral -** *Effective 1/1/2021*		
No PA Required Diclofenac 1.5% topical solution VOLTAREN (diclofenac) 1% gel	**PA Required** Diclofenac 1.3% topical patch (generic Flector) FLECTOR (diclofenac) 1.3% topical patch	**SPRIX (ketorolac)** may be approved if meeting the following criteria: ● Member is unable to tolerate, swallow or absorb oral NSAID formulations **OR** ● Member has trialed and failed three preferred oral or topical NSAID agents (failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions) ● Quantity limit: 5-single day nasal spray bottles per 30 days

Diclofenac sodium 1% (generic Voltaren) gel	Ketorolac nasal spray LICART (diclofenac) 1.3% topical patch PENNSAID (diclofenac solution) 2% Pump, 2% Solution Packet SPRIX (ketorolac) nasal spray	All other non-preferred topical agents may be approved for members who have trialed and failed one preferred agent. Failure is defined as lack of efficacy with 14 day trial, allergy, intolerable side effects, or significant drug-drug interaction. **FLECTOR (diclofenac)** patch quantity limit: 2 patches per day **SOLARAZE (diclofenac sodium)** gel prior authorization criteria can be found on the Appendix P.

Opioid Utilization Policy (long-acting and short-acting opioids):

It is highly encouraged that the healthcare team utilize the Prescription Drug Monitoring Program (PDMP) to aid in ensuring safe and efficacious therapy for members using controlled substances.

Total Morphine Milligram Equivalent Policy Effective 10/1/17:

- The maximum allowable morphine milligram equivalent (MME) is 200 MME. Prescriptions for short-acting (SA) and long-acting (LA) opioids are cumulatively included in this calculation. The prescription that exceeds the cumulative MME limit of 200 MME for a member will require prior authorization and may require a provider to provider telephone consultation with the pain management physician (free of charge and provided by Health First Colorado).
- Prior authorization will be granted to allow for tapering
- Prior authorization for 1 year will be granted for diagnosis of sickle cell anemia
- Prior authorization for 1 year will be granted for admission to or diagnosis of hospice or end of life care
- Prior authorization for 1 year will be granted for pain associated with cancer

MME calculation is conducted using conversion factors from the following website: http://agencymeddirectors.wa.gov/Calculator/DoseCalculator.htm

Only one long-acting opioid agent (including different strengths) and one short-acting opioid agent (including different strengths) will be considered for a prior authorization.

Medicaid provides guidance on the treatment of pain, including tapering, on our webpage under the heading Pain Management Resources and Opioid Use at: https://www.colorado.gov/pacific/hcpf/pain-management-resources-and-opioid-use

Opioid Naïve Policy Effective 8/1/17 (*Update effective 11/27/19 in Italics*):
Members who have not filled a prescription for an opioid within the past 180 days will be identified as "opioid treatment naïve" and have the following limitations placed on the initial prescription(s):

- The prescription is limited to short-acting opioid agents *or Butrans (buprenorphine) 5mcg patch*. *Use of other* long-acting opioid agents will require prior authorization approval for members identified as opioid treatment naïve.
- The days supply of the first, second, and third prescription for an opioid will be limited to 7 days, the quantity will be limited to 8 dosage forms per day (tablets, capsules), maximum #56 tablets/capsules for a 7 day supply
- The fourth prescription for an opioid will require prior authorization, filling further opioid prescriptions may require a clinical pharmacist review or provider to provider telephone consultation with a pain management physician (free of charge and provided by Health First Colorado).
- If a member has had an opioid prescription filled within the past 180 days, then this policy would not apply to that member and other opioid policies would apply as applicable.

Dental Prescriptions Opioid Policy Effective 11/15/18 (implemented in the claims system 01/07/19):
Members who receive an opioid prescribed by a dental provider will be subject to day supply limits and quantity per day limits for short acting opioids.

- The prescription is limited to short-acting opioid agents only. Use of long-acting opioid agents and short acting fentanyl agents will require prior authorization approval for members' prescriptions written by a dental provider.
- The days supply of the first, second, and third prescription for an opioid will be limited to 4 days, the quantity will be limited to 6 dosage forms per day (tablets, capsules), maximum #24 tablets/capsules for a 4 day supply
- The fourth prescription for an opioid will require prior authorization. A prior authorization for the fourth fill may be approved for up to a 7 day supply and the quantity will be limited to 8 dosage forms per day (#56 tablets/capsules) for members with any of the following diagnoses/undergoing any of the following procedures:
    - Traumatic oro-facial tissue injury with major mandibular/maxillary surgical procedures
    - Severe cellulitis of facial planes
    - Severely impacted teeth with facial space infection necessitating surgical management
- Other potential exemptions that exceed the first 3 fill limits (day supply and quantity) may be evaluated with a provider to provider telephone consult with a pain management specialist (free of charge and provided by Health First Colorado)

If a member has had an opioid prescription prescribed by a non-dental provider, then this policy would not apply to that member and other opioid policies would apply as applicable. Dental prescriptions do not impact the opioid treatment naïve policy, but the prescriptions will be counted towards the Morphine Milligram Equivalent (MME) daily dose.

Opioid and Benzodiazepine Combination Effective 9/15/19:
Prior authorization will be required for members receiving long-term therapy with an opioid medication who are newly started on a benzodiazepine medication OR for members receiving long-term therapy with a benzodiazepine medication who are newly started on an opioid medication. Prior authorization may be approved if meeting the following:

- The member discontinued or is no longer taking either the opioid or benzodiazepine medication and will not be using these in combination **OR**
- The member will not be taking the prescribed opioid and benzodiazepine medications at the same time based on prescribed dosing interval (such as prn administration) for the regimen AND the prescriber attests that the member has received appropriate counseling* regarding the risks associated with combining opioid and benzodiazepine medications including increased risk for sedation, respiratory depression, overdose, and overdose-related death and counseling regarding the FDA Boxed Warning for combining these medications **OR**
- The prescriber has evaluated the regimen and attests that it is appropriate for the member to continue use of the concomitant opioid and benzodiazepine medication regimen as prescribed AND the prescriber attests that the member has received appropriate counseling* regarding the risks associated with combining opioid and benzodiazepine medications including increased risk for sedation, respiratory depression, overdose, and overdose-related death and counseling regarding the FDA Boxed Warning for combining these medications **OR**
- Prior authorization may be approved for members receiving palliative or hospice care **OR**
- For benzodiazepine prior authorizations, approval may be granted if the benzodiazepine is being prescribed for seizure disorder or convulsions.

**If counseling has not been provided, the prescriber attests that a reasonable effort will be made to contact the member or the member's pharmacy to ensure that counseling is provided.*

Opioid and Quetiapine Combination Effective 9/15/19:
Pharmacy claims for members receiving opioid and quetiapine medications in combination will require entry of point-of-sale DUR service codes (Reason for Service, Professional Service, Result of Service) for override of drug-drug interaction (DD) related to risk of increased sedation from concomitant use of this drug combination.

Therapeutic Drug Class: **OPIOIDS, Short Acting** - *Effective 7/1/2020*		
No PA Required* (if criteria and quantity limit is met)	**PA Required**	
Acetaminophen/codeine tablets*	Acetaminophen / codeine elixir APADAZ (benzhydrocodone/ acetaminophen)	*Preferred codeine and tramadol products do not require prior authorization for adult members (18 years of age or greater) if meeting all other opioid policy criteria. Preferred codeine or tramadol products prescribed for members < 18 years of age must meet the following criteria:

Hydrocodone/acetaminophen solution, tablet Hydromorphone tablet Morphine IR solution, tablet Oxycodone solution, tablet Oxycodone/acetaminophen tablet Tramadol 50mg* Tramadol/acetaminophen tablet*	ASCOMP WITH CODEINE (codeine/ butalbital/aspirin/caffeine) Benzhydrocodone/acetaminophen Butalbital/caffeine/acetaminophen/ codeine* Butalbital compound w/ codeine Butorphanol tartrate (nasal) Carisoprodol/aspirin/codeine Codeine tablet DILAUDID (hydromorphone) (all forms) DVORAH (acetaminophen/caffeine/ dihydrocodeine) Fiorinal/codeine Hydrocodone/ibuprofen Hydromorphone liquid IBUDONE (hydrocodone/ibuprofen) Levorphanol LORTAB (hydrocodone/ acetaminophen) elixir Meperidine solution, tablet Morphine concentrated solution, oral syringe NALOCET (oxycodone/ acetaminophen) NORCO (hydrocodone/acetaminophen) NUCYNTA** (tapentadol)	• **Preferred tramadol and tramadol-containing products** may be approved for members < 18 years of age if meeting the following: o Member is ≥ 12 years of age AND o Tramadol is NOT being prescribed for post-surgical pain following tonsil or adenoid procedure AND o Member is not obese (BMI greater than 30kg/m2) and does not have obstructive sleep apnea or severe lung disease o OR o For members < 12 years of age with complex conditions or life-limiting illness who are receiving care under a pediatric specialist, tramadol and tramadol-containing products may be approved on a case-by-case basis • **Preferred Codeine and codeine-containing products** will receive prior authorization approval for members meeting the following criteria may be approved for members < 18 years of age if meeting the following: o Member is ≥ 12 years of age AND o Codeine is NOT being prescribed for post-surgical pain following tonsil or adenoid procedure AND o Member is not obese (BMI greater than 30kg/m2) and does not have obstructive sleep apnea or severe lung disease AND o Member is not pregnant or breastfeeding AND o Renal function is not impaired (GFR > 50 ml/min) AND o Member is not receiving strong inhibitors of CYP3A4 (e.g, erythromycin, clarithromycin, telithromycin, itraconazole, ketoconazole, posaconazole, fluconazole [≥200mg daily], voriconazole, delavirdine, and milk thistle) AND o Member meets <u>one</u> of the following: ▪ Member has trialed codeine or codeine-containing products in the past no history of allergy or adverse drug reaction to codeine ▪ Member has not trialed codeine or codeine-containing products in the past and the prescriber acknowledges reading the following statement: "Approximately 1-2% of the population metabolizes codeine in a manner that exposes them to a much higher potential for toxicity. Another notable proportion of the population may not clinically respond to codeine. We ask that you please have close follow-up with members newly starting codeine and codeine-containing products to monitor for safety and efficacy." **Nucynta® IR** (tapentadol) may be approved for members who meet the following criteria: ● Member has history of trial/failure of 7-days utilization of preferred product(s)in the last 21 days OR ● If member does not meet the above criteria, prior authorization approval for Nucynta IR will require trial and failure of three preferred agents. Failure is defined as lack of efficacy, intolerable side effects, significant drug-drug interaction, allergy‡, or significant adverse drug reaction. ● Nucynta IR will have a maximum daily quantity of 6 tablets (180 tabs per 30 days).

	OPANA (oxymorphone) OXAYDO (oxycodone) Oxycodone/aspirin Oxycodone/acetaminophen solution Oxycodone/ibuprofen Oxycodone capsule, syringe, conc solution Oxymorphone tablet Pentazocine/naloxone PERCOCET (oxycodone/ acetaminophen) PRIMLEV (oxycodone/acetaminophen) ROXICODONE (oxycodone) tablet ROXYBOND (oxycodone) Tramadol 100mg ULTRACET (tramadol/ acetaminophen) ULTRAM (tramadol)	Non-preferred tramadol products may be approved following trial and failure of generic tramadol 50mg tablet AND generic tramadol/acetaminophen tablet. All other non-preferred short-acting opioid products may be approved following trial and failure of three preferred products. Failure is defined as allergy‡, lack of efficacy, intolerable side effects, or significant drug-drug interaction. ‡Allergy: hives, maculopapular rash, erythema multiforme, pustular rash, severe hypotension, bronchospasm, and angioedema <u>Quantity Limits</u>: Short-acting opioids will be limited to a total of 120 tablets per 30 days (4/day) per member for members who are not included in the opioid treatment naive policy. Exceptions will be made for members with a diagnosis of a terminal illness (hospice or palliative care) or sickle cell anemia. For members who are receiving more than 120 tablets currently and who do not have a qualifying exemption diagnosis, a 6-month prior authorization can be granted via the prior authorization process for providers to taper members. Please note that if more than one agent is used, the combined total utilization may not exceed 120 units in 30 days. There may be allowed certain exceptions to this limit for acute situations (for example: post-operative surgery, fractures, shingles, car accident). <u>Maximum Doses:</u> Tramadol: 400mg/day Codeine: 360mg/day Butorphanol intranasal: 10ml per 30 days (four 2.5ml 10mg/ml package units per 30 days)
Therapeutic Drug Class: **FENTANYL PREPARATIONS (buccal, intranasal, transmucosal, sublingual)** - *Effective 7/1/2020*		
	PA Required ABSTRAL (fentanyl citrate) ACTIQ (fentanyl citrate) Fentanyl citrate FENTORA (fentanyl citrate)	Fentanyl buccal, intranasal, transmucosal, and sublingual products: Prior authorization approval may be granted for members experiencing breakthrough cancer pain and those that have already received and are tolerant to opioid drugs for the cancer pain AND are currently being treated with a long-acting opioid drug. The prior authorization may be granted for up to 4 doses per day. For patients in hospice or palliative care, prior authorization will be automatically granted regardless of the number of doses prescribed. Ionsys transdermal system requires administration in the hospital setting and is not covered under the pharmacy benefit

Therapeutic Drug Class: **OPIOIDS, Long Acting** - *Effective 7/1/2020*		
No PA Required (*if dose met) BUTRANS (buprenorphine) transdermal patch [BNR] *Fentanyl 12mcg, 25mcg, 50mcg, 75mcg, 100mcg transdermal patch Morphine ER (generic MS Contin) tablet Tramadol ER (generic Ultram ER) tablet	**PA Required** *NUCYNTA ER (tapentadol ER) *OXYCONTIN (oxycodone ER) tablet ARYMO ER (morphine) tablet BELBUCA (buprenorphine) buccal film Buprenorphine transdermal patch CONZIP (tramadol ER) capsule DOLOPHINE (methadone) DURAGESIC (fentanyl) transdermal patch Fentanyl 37mcg, 62mcg, 87mcg transdermal patch Hydrocodone ER capsule Hydromorphone ER tablet HYSINGLA (hydrocodone ER) tablet KADIAN (morphine ER) capsule Methadone (all forms) MORPHABOND (morphine ER) tablet Morphine ER capsules MS CONTIN (morphine ER) tablet Oxycodone ER tablet Oxymorphone ER tablet Tramadol ER (generic Ryzolt/Conzip) XTAMPZA ER (oxycodone) capsule	*__Nucynta ER__ or __Oxycontin__ may be approved for members who have trialed and failed‡ treatment with TWO preferred agents. All other non-preferred products may be approved for members who have trialed and failed‡ three preferred products. ‡Failure is defined as lack of efficacy with 14 day trial due to allergy (hives, maculopapular rash, erythema multiforme, pustular rash, severe hypotension, bronchospasm, and angioedema), intolerable side effects, or significant drug-drug interaction. <u>Methadone Continuation:</u> Members who have been receiving methadone for pain indications do not have to meet non-preferred criteria. All new starts for methadone will require prior authorization under the non-preferred criteria listed above. *If a prescriber would like to discuss strategies for tapering off methadone or transitioning to other pain management therapies for a Health First Colorado member, consultation with the Health First Colorado pain management physician is available free of charge by contacting the pharmacy call center helpdesk and requesting an opioid prescriber consult.* <u>Reauthorization:</u> Reauthorization for a non-preferred agent may be approved if the following criteria are met: ● Provider attests to continued benefit outweighing risk of opioid medication use AND ● Member met original prior authorization criteria for this drug class at time of original authorization <u>Quantity/Dosing Limits:</u> ● **Oxycontin, Opana ER, Nucynta ER,** and **Zohydro ER** will only be approved for twice daily dosing. ● **Hysingla ER** will only be approved for once daily dosing. ● **Fentanyl patches** will require a PA for doses of more than 15 patches/30 days (taking one strength) or 30 patches for 30 days (taking two strengths). For fentanyl patch strengths of 37mcg/hr, 62mcg/hr, and 87mcg/hr. Member must trial and fail two preferred strengths of separate patches summing desired dose (i.e. 12mcg/hr + 50mcg/hr =62mcg/hr)

	ZOHYDRO ER (hydrocodone) capsule	

II. Anti-Infectives

Therapeutic Drug Class: **ANTIBIOTICS, INHALED** -*Effective 1/1/2021*

No PA Required (*Must meet eligibility criteria)	**PA Required**	
Tobramycin inhalation solution (generic TOBI) *CAYSTON (aztreonam) inhalation solution	Arikayce (amikacin liposomal) inhalation vial Bethkis (tobramycin) inhalation ampule Kitabis (tobramycin) nebulizer pak TOBI (tobramycin) inhalation solution TOBI PODHALER (tobramycin) inhalation capsule Tobramycin inhalation ampule Tobramycin nebulizer pak	*__CAYSTON (aztreonam)__ inhalation solution may be approved if the following criteria are met: • Member has a history of trial and failure of preferred tobramycin solution for inhalation (failure is defined as lack of efficacy with a 4-week trial, intolerable side effects, or significant drug-drug interactions) **OR** provider attests that member cannot use preferred tobramycin solution for inhalation due to documented allergy or contraindication to therapy **AND** • The member has known colonization of *Pseudomonas aeruginosa* in the lungs **AND** • The member has been prescribed an inhaled beta agonist to use prior to nebulization of Cayston (aztreonam). **ARIKAYCE (amikacin)** may be approved if the following criteria are met: • Member has refractory mycobacterium avium complex (MAC) lung disease with limited or no alternative treatment options available **AND** • Member has trialed and failed 6 months of therapy with a 3-drug regimen that includes a macrolide (failure is defined as lack of efficacy, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interactions). All other non-preferred inhaled antibiotic agents may be approved if the following criteria are met: • The member has a diagnosis of cystic fibrosis with known colonization of *Pseudomonas aeruginosa* in the lungs **AND** • Member has history of trial and failure of preferred tobramycin solution for inhalation (failure is defined as lack of efficacy with a 4-week trial, contraindication to therapy, allergy, intolerable side effects or significant drug-drug interactions). **Table 1: Minimum Age, Maximum Dose, and Quantity Limitations** | | **Minimum Age** | **Maximum Dose** | **Quantity Limit (based on day supply limitation for pack size dispensed)** | | ARIKAYCE (amikacin) | ≥ 18 years | 590 mg daily | Not applicable | | BETHKIS (tobramycin) | Age ≥ 6 years | 300 mg twice daily | 28-day supply per 56 day period |

CAYSTON (aztreonam)	≥ 7 years	225 mg daily	28-day supply per 56 day period
KITABIS PAK (tobramycin)	Age ≥ 6 years	300 mg twice daily	28-day supply per 56 day period
TOBI † (tobramycin)	Age ≥ 6 years	300 mg twice daily	28-day supply per 56 day period
TOBI PODHALER (tobramycin)	Age ≥ 6 years	112 mg twice daily	28-day supply per 56 day period
† *Limitations apply to brand product formulation only*			

Grandfathering: Members currently stabilized on any inhaled antibiotic agent in this class may receive approval to continue on that agent.

Therapeutic Drug Class: **ANTI-HERPETIC AGENTS - Oral -***Effective 1/1/2021*

No PA Required	**PA Required**	
Acyclovir tablet, capsule	SITAVIG (acyclovir) buccal tablet	Non-preferred products may be approved for members who have failed an adequate trial with two preferred products with different active ingredients. Failure is defined as lack of efficacy with 14 day trial, allergy, intolerable side effects, or significant drug-drug interaction.
Acyclovir suspension *(members under 5 years or with a feeding tube)*	VALTREX (valacyclovir) tablet	Sitavig (acyclovir) buccal tablet may be approved for diagnosis of recurrent herpes labialis (cold sores) if member meets non-preferred criteria listed above AND has failed trial with oral acyclovir suspension. Failure is defined as lack of efficacy with 14 day trial, allergy, intolerable side effects, or significant drug-drug interaction.
Famciclovir tablet	ZOVIRAX (acyclovir) capsule, tablet	
Valacyclovir tablet		For members with a diagnosis of Bell's palsy, valacyclovir 1000 mg three times daily will be approved for 7 days if member presents with severe facial palsy.
		Acyclovir suspension may be approved for: • Members under 5 years of age OR • Members with a feeding tube OR • Members meeting non-preferred criteria listed above.

Maximum Dose Table		
	Adult	**Pediatric**
Acyclovir	4000 mg daily	3200 mg daily
Valacyclovir	4000 mg daily	Age 2-11 years: 3000mg daily Age ≥ 12 years: 4000mg daily

Therapeutic Drug Class: **ANTI-HERPETIC AGENTS- Topical -** *Effective 1/1/2021*

No PA Required	**PA Required**	
DENAVIR (penciclovir) cream	Acyclovir cream	**Generic Acyclovir ointment/cream** will be approved for members who have failed an adequate trial with Zovirax ointment/cream (diagnosis, dose and duration) as deemed by approved compendium. (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction)
ZOVIRAX**BNR** (acyclovir) cream	Acyclovir ointment	

ZOVIRAX[BNR] (acyclovir) ointment	XERESE (acyclovir/hydrocortisone) cream	**Xerese** (acyclovir/hydrocortisone) prior authorization will be approved for members that meet the following criteria: ● Documented diagnosis of recurrent herpes labialis AND ● Member is immunocompetent AND ● Member has failed treatment of at least 10 days with acyclovir (Failure will be defined as significant drug-drug interaction, lack of efficacy, contraindication to or intolerable side effects) AND ● Member has failed treatment of at least one day with famciclovir 1500 mg OR valacyclovir 2 GM twice daily (Failure is defined as significant drug-drug interaction, lack of efficacy, contraindication to or intolerable side effects)
Therapeutic Drug Class: **FLUOROQUINOLONES -Oral** -*Effective 1/1/2021*		
No PA Required *CIPRO (ciprofloxacin) oral suspension (<5 years old) *Ciprofloxacin oral suspension (<5 years old) Ciprofloxacin tablet Levofloxacin tablet	**PA Required** AVELOX (moxifloxacin) tablet BAXDELA (delafloxacin) tablet CIPRO (ciprofloxacin) tablet Ciprofloxacin oral suspension (>5 years old), ER tablet Levofloxacin oral solution Moxifloxacin tablet Ofloxacin tablet	*__CIPRO (ciprofloxacin) suspension__ may be approved for members < 5 years of age without prior authorization. For members ≥ 5 years of age, CIPRO (ciprofloxacin) suspension may be approved for members who cannot swallow a whole or crushed tablet. Non-preferred products may be approved for members who have failed an adequate trial (7 days) with at least one preferred product. (Failure is defined as: lack of efficacy, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction). **Levofloxacin solution** may be approved for members < 5 years of age with prescriber attestation that member is unable to take Cipro (ciprofloxacin) crushed tablet or suspension OR for members < 5 years of age for treatment of pneumonia. For members ≥ 5 years of age, levofloxacin solution may be approved for members who require administration via feeding tube OR who have failed an adequate trial (7 days) of ciprofloxacin suspension. Failure is defined as lack of efficacy, allergy, intolerable side effects, significant drug-drug interaction, or contraindication to therapy.
Therapeutic Drug Class: **HEPATITIS C VIRUS TREATMENTS** - *Effective 1/1/2021*		
Direct Acting Antivirals (DAAs)		
PA Required for all agents in this class Prior authorization requests must be submitted via the Hepatitis C specific PAR form which can be accessed on the Pharmacy Resources page at: https://www.colorado.gov/hcpf/pharmacy-resources		
EPCLUSA[BNR] 200mg -50mg (sofosbuvir/velpatasvir) HARVONI [BNR] 45mg-200mg tablets, pellets (ledipasvir/sofosbuvir)	SOVALDI (sofosbuvir) VIEKIRA PAK (ombitasvir/paritaprevir/ ritonavir/dasabuvir) tablet ZEPATIER (elbasvir/grazoprevir)	

Preferred Hepatitis C Virus Treatment Regimens	
Harvoni tablet (ledipasvir/sofosbuvir)	May be approved for members 3 years and older for GT 1, 4-6 who are NC, have CC; or GT 1 in combination with ribavirin in DC; or GT 1,4 in combination with ribavirin for liver transplant recipients who are NC, have CC; AND meet the below applicable criteria
Mavyret tablet (glecapravir/pibrentasvir)	May be approved for members 12 years and older or weighing at least 45 kg GT 1-6 who are NC or have CC (Child-Pugh A), AND meet the below applicable criteria
Epclusa tablet (sofosbuvir/velpatasvir)	May be approved for members 6 years and older or weighing at least 17 kg for GT 1-6 who are NC, have CC (Child-Pugh A); or in combination with ribavirin in DC; AND meet the below applicable criteria

Ledipasvir/Sofosbuvir 90mg-400mg tablet (*Asequa only)*

MAVYRET (glecaprevir/pibrentasvir)

Sofosbuvir/Velpatasvir 400mg-100mg (*Asequa only)*

VOSEVI [2nd Line] (sofosbuvir/velpatasvir/ voxilaprevir)

Harvoni pellet (ledipasvir/sofosbuvir)	May be approved for members 3 years of age or older weighing less that 17kg OR members 3 years of age or older that are unable to take/swallow ledipasvir/sofosbuvir oral tablets AND meeting one of the following: • GT 1, 4-6 who are NC, have CC • GT 1 in combination with ribavirin in DC • GT 1,4 in combination with ribavirin for liver transplant recipients who are NC, have CC AND meet the below applicable criteria.

Body Weight	Dosing	Maximum Daily Dose
< 17 kg	one 33.75mg/150mg packet once daily x 12 weeks	33.75mg/150mg
17- 34 kg	one 45mg/200mg packet once daily x 12 weeks	45mg/200mg
≥ 35 kg	two 45mg/200mg packets once daily x 12 weeks	90mg/400 mg

Vosevi tablet[2nd Line] (sofosbuvir/velpatasvir/ voxilaprevir)	May be approved for members 18 years or older with chronic HCV infection who are NC, have CC (Child-Pugh A) AND meet one of the following: • GT 1-6 and has previously failed treatment with a regimen containing an NS5A inhibitor (such as ledipasvir, daclatasvir, or ombitasvir) OR • GT 1a or 3 and has previously failed treatment with a regimen containing sofosbuvir without an NS5A inhibitor AND meet the below applicable criteria for retreatment.

(GT-Genotype, NC-Non-Cirrhotic, CC-Compensated Cirrhosis, DC-Decompensated Cirrhosis)

Initial Treatment (all agents):

Preferred agents may be approved for initial treatment if the following criteria are met:

- Physician attests that one quantitative HCV RNA test result from 12-24 weeks post-treatment will be provided in order to document SVR (sustained virologic response) **AND**
- Member must have received, or be in the process of receiving, full courses of both Hepatitis A and Hepatitis B vaccinations, or have immunity **AND**
- If a non-pan genotypic DAA will be prescribed, then test for HCV genotype and subtype. Members must have genotyping results within 1 year prior to the anticipated therapy start date **AND**
- If member is abusing/misusing alcohol or controlled substances, member must be receiving counseling or will be enrolled in counseling or a substance use treatment program prior to initiation of treatment for HCV infection **AND**
- Agent must be prescribed by an infectious disease specialist, gastroenterologist, or hepatologist **OR** prescribed by any primary care provider in consultation with an infectious disease specialist, gastroenterologist or hepatologist **OR** for treatment naïve members without cirrhosis, prescribed by any primary care who has completed the hepatitis C (HCV) ECHO series (four, 1-hour trainings) **AND**

		• Physician attests to the member's readiness for adherence to treatment (prescribers may utilize assessment tools to evaluate readiness of the patient for treatment. Some examples are available at: https://www.thenationalcouncil.org/wp-content/uploads/2020/04/Screening-for-Viral-Hepatitis-within-Behavioral-Health-Organizations-7.9.14.pdf?daf=375ateTbd56 or Psychosocial Readiness Evaluation and Preparation for Hepatitis C Treatment (PREP-C) available at: https://prepc.org/) **AND** • Member's complete current medication list has been reviewed and screened for significant drug-drug interactions (reference tool available at https://www.hep-druginteractions.org/) **AND** • Physician attests to meeting one of the following: o Member has a diagnosis of chronic HCV infection (presence of HCV RNA viral load for ≥ 6 months) OR o Member has a diagnosis of acute HCV infection in the setting of solid organ transplant OR o Prescriber wishes to treat a member with acute HCV infection upon initial diagnosis and acknowledges that the rate of spontaneous resolution of acute infection has been considered as part of assessing the need to initiate antiviral therapy (acute HCV infection may spontaneously clear in 20-50% of patients) **AND** • For women of childbearing potential, pregnancy test results have been documented within 30 days of expected direct-acting antiviral start date, and counseling has been provided regarding pregnancy and breastfeeding **AND** • The following laboratory tests and assessments conducted within 6 months of initiating therapy have been provided: o Quantitative HCV-RNA o Complete Blood Count (CBC) o Hepatic Function Panel (i.e. albumin, total and direct bilirubin, alanine aminotransferase (ALT), aspartate aminotransferase (AST), and alkaline phosphatase levels) o Calculated glomerular filtration rate (GFR) o If cirrhosis is present, calculation of the Child-Turcotte-Pugh (CTP) Score o Transplant status as applicable (pre-, post-, N/A) All other non-preferred agents may be approved if the criteria for initial treatment above is satisfied **AND** documentation is provided indicating an acceptable rationale for not prescribing a preferred treatment regimen (acceptable rationale may include patient-specific medical contraindications to a preferred treatment or cases where a member has initiated treatment on a non-preferred drug and needs to complete therapy). **Re-treatment:**

		All requests for HCV re-treatment for members who have failed therapy with a DAA will be reviewed on a case-by-case basis. Additional information will be requested for retreatment requests including (but not limited to): • Previous regimen medications and dates treated • Genotype of previous HCV infection • Any information regarding adherence to previously trialed regimen(s) and current chronic medications • Adverse effects experienced from previous treatment regimen • Concomitant therapies during previous treatment regimen • Vosevi regimens will require verification that member has been tested for evidence of active hepatitis B virus (HBV) infection and for evidence of prior HBV infection prior to initiating treatment. **For ribavirin-containing regimens only:** • Member is not a pregnant female or a male with a pregnant female partner **AND** • Women of childbearing potential and their male partners must attest that they will use two forms of effective (non-hormonal) contraception during treatment **AND** • Member does not meet any of the following ineligibility criteria for use of ribavirin: • Pregnant women and men whose female partners are pregnant • Known hypersensitivity to ribavirin • Autoimmune hepatitis • Hemoglobinopathies • Creatinine Clearance < 50mL/min • Co-administered with didanosine **Grandfathering:** Members currently receiving treatment with a non-preferred agent will receive approval to finish their treatment regimen, provided required documentation is sent via normal PAR process.
Ribavirin Products		
No PA Required Ribavirin capsule Ribavirin tablet	**PA Required** RIBASPHERE (ribavirin)	Non-preferred ribavirin products require prior authorizations which will be evaluated on a case-by-case basis. Members currently receiving non-preferred ribavirin product will receive approval to continue that product for the duration of their HCV treatment regimen.
Therapeutic Drug Class: **TETRACYCLINES -** *Effective 7/1/2020*		
No PA Required Doxycycline hyclate capsules Doxycycline hyclate tablets	**PA Required** Demeclocycline tablet DORYX (doxycycline DR) tablet	Prior authorization for non-preferred tetracycline agents may be approved if member has trialed/failed a preferred doxycycline product AND preferred minocycline. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.

Doxycycline monohydrate 50mg, 100mg capsule Doxycycline monohydrate tablets Minocycline capsules	Doxycycline hyclate DR tablet Doxycycline monohydrate 40mg, 75mg, 150mg capsule Doxycycline monohydrate Suspension MINOCIN (minocycline) capsule Minocycline IR, ER tablet MINOLIRA (minocycline) NUZYRA (omadacycline)* SOLODYN ER (minocycline) Tetracycline capsule VIBRAMYCIN (doxycycline) suspension, syrup XIMINO ER (minocycline)	Prior authorization for liquid oral tetracycline formulations may be approved if member has difficulty swallowing and cannot take solid oral dosage forms. **Nuzyra** (omadacycline) prior authorization may be approved if member meets all of the following criteria: the above "non-preferred" prior authorization criteria and the following: • Member has trialed and failed† therapy with a preferred doxycycline product and preferred minocycline OR clinical rationale is provided describing why these medications cannot be trialed (including resistance and sensitivity) AND • Member has diagnosis of either Community Acquired Bacterial Pneumonia (CABP) or Acute Bacterial Skin and Skin Structure Infection (ABSSSI) or clinical rationale and supporting literature describing/supporting intended use AND one of the following: o If member diagnosis is ABSSSI, member must have trial and failure† of sulfamethoxazole/trimethoprim product in addition to preferred tetracyclines OR o If member diagnosis is CABP, member must have trial and failure† of either a beta-lactam antibiotic (amoxicillin/clavulanic acid) or a macrolide (azithromycin) AND • Maximum duration of use is 14 days †Failure is defined as lack of efficacy with 7 day trial, allergy, intolerable side effects, or significant drug-drug interaction.)

III. Cardiovascular

Therapeutic Drug Class: **ANGIOTENSIN MODIFIERS** - *Effective 7/1/2020*

Angiotensin-converting enzyme inhibitors (ACE Inh)

No PA Required	**PA Required**	
Benazepril tablet Enalapril tablet Fosinopril tablet Lisinopril tablet Quinapril tablet Ramipril tablet	ACCUPRIL (quinapril) tablet ALTACE (ramipril) capsule Captopril EPANED powder/solution* (enalapril) LOTENSIN (benazepril) tablet Moexipril tablet Perindopril tablet	Non-preferred ACE inhibitors, ACE inhibitor combinations, ARBs, ARB combinations, renin inhibitors, and renin inhibitor combination products may be approved for members who have trialed and failed treatment with three preferred products (failure is defined as lack of efficacy with a 4 week trial, allergy, intolerable side effects, or significant drug-drug interaction). ***Epaned** (enalapril) solution may be approved without trial and failure of three preferred agents for members under the age of 5 years who cannot swallow a whole or crushed tablet. ***Qbrelis** (lisinopril) solution may be approved for members 6 years of age or older who cannot swallow a whole or crushed tablet and have trialed and failed Epaned (enalapril) solution. Failure is defined as lack of efficacy with a 4 week trial, allergy, intolerable side effects, or significant drug-drug interaction.

	PRINIVIL (lisinopril) tablet QBRELIS (lisinopril) solution* Trandolapril tablet VASOTEC (enalapril) tablet ZESTRIL (lisinopril) tablet	
ACE Inh Combinations		
No PA Required Enalapril HCTZ Lisinopril HCTZ	**PA Required** ACCURETIC (quinapril HCTZ) Benazepril HCTZ Captopril HCTZ Fosinopril HCTZ LOTENSIN HCT (benazepril HCTZ) Quinapril HCTZ VASERETIC (enalapril HCTZ) ZESTORETIC (lisinopril HCTZ)	Non-preferred ACE inhibitors, ACE inhibitor combinations, ARBs, ARB combinations, renin inhibitors, and renin inhibitor combination products may be approved for members who have trialed and failed treatment with three preferred products (failure is defined as lack of efficacy with a 4 week trial, allergy, intolerable side effects, or significant drug-drug interaction).
Angiotensin II receptor blockers (ARBs)		
No PA Required Irbesartan Losartan Olmesartan Telmisartan Valsartan	**PA Required** ATACAND (candesartan) AVAPRO (irbesartan) BENICAR (olmesartan) Candesartan COZAAR (losartan) DIOVAN (valsartan)	Non-preferred ACE inhibitors, ACE inhibitor combinations, ARBs, ARB combinations, renin inhibitors, and renin inhibitor combination products may be approved for members who have trialed and failed treatment with three preferred products (failure is defined as lack of efficacy with a 4 week trial, allergy, intolerable side effects, or significant drug-drug interaction).

	Eprosartan MICARDIS (telmisartan)	
ARB Combinations		
No PA Required Amlodipine/olmesartan Amlodipine/valsartan Irbesartan/HCTZ Losartan/HCTZ Olmesartan/HCTZ Valsartan/HCTZ	**PA Required** Amlodipine/valsartan/HCTZ ATACAND HCT (candesartan/HCTZ) AVALIDE (irbesartan/HCTZ) AZOR (amlodipine/olmesartan) BENICAR HCT (olmesartan/HCTZ) BYVALSON (nebivolol/valsartan) Candesartan/HCTZ DIOVAN HCT (valsartan/HCTZ) EDARBYCLOR (azilsartan/chlorthalidone) EXFORGE (amlodipine/valsartan) EXFORGE HCT (amlodipine/valsartan/ HCTZ) HYZAAR (losartan/HCTZ) MICARDIS HCT (telmisartan/HCTZ) Olmesartan/amlodipine/HCTZ Telmisartan/amlodipine Telmisartan/HCTZ TRIBENZOR (amlodipine/olmesartan/ HCTZ)	Non-preferred ACE inhibitors, ACE inhibitor combinations, ARBs, ARB combinations, renin inhibitors, and renin inhibitor combination products may be approved for members who have trialed and failed treatment with three preferred products (failure is defined as lack of efficacy with a 4-week trial, allergy, intolerable side effects, or significant drug-drug interaction).
Renin Inhibitors & Renin Inhibitor Combinations		

	PA Required Aliskiren TEKTURNA (aliskiren) TEKTURNA HCT (aliskiren/HCTZ)	Non-preferred renin inhibitors and renin inhibitor combination products may be approved for members who have failed treatment with three preferred products from the angiotensin modifier class (failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction). Renin inhibitors and combinations will not be approved in patients with diabetes. Renin inhibitors are contraindicated when used in combination with an ACE-inhibitor, ACE-inhibitor combination, ARB, or ARB-combination.
Therapeutic Drug Class: **PULMONARY ARTERIAL HYPERTENSION THERAPIES -** *Effective 1/1/2021*		
Phosphodiesterase Inhibitors		
***Must meet eligibility criteria** *Sildenafil **(**generic Revatio) 20 mg tablet *Tadalafil 20mg tablet	**PA Required** ADCIRCA (tadalafil) tablet ALYQ (tadalafil) 20mg tablet REVATIO (sildenafil) 20mg tablet, suspension Sildenafil (generic Revatio) oral suspension	***Eligibility Criteria for all agents in the class** Approval will be granted for a diagnosis of pulmonary hypertension. Non-preferred products may be approved for members who have failed treatment with preferred sildenafil AND preferred tadalafil. Failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects, or significant drug-drug interaction. **Revatio (sildenafil) suspension** will approved for members who are unable to take/swallow tablets **Grandfathering:** Members who have been previously stabilized on a non-preferred product can receive approval to continue on the medication.
Endothelin Antagonists		
***Must meet eligibility criteria** *LETAIRIS[BNR] (ambrisentan) tablet *TRACLEER 62.5mg, 125mg (bosentan) tablet [BNR]	**PA Required** Ambrisentan (generic Letairis) tablet Bosentan (generic Tracleer) 62.5mg, 125mg tablet OPSUMIT (macitentan) TRACLEER (bosentan) 32mg tablet for suspension	***Eligibility Criteria for all agents in the class** Approval will be granted for a diagnosis of pulmonary hypertension. Member and prescriber should be enrolled in applicable REMS program for prescribed medication. Non-preferred agents will be approved for members who have trialed and failed two preferred agents. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. **Grandfathering:** Members who have been previously stabilized on a Non-preferred product can receive approval to continue on the medication.
Prostanoids		
***Must meet eligibility criteria** *Epoprostenol (generic Flolan) vial *ORENITRAM (treprostinil) ER tablet	**PA Required** FLOLAN (epoprostenol) vial REMODULIN (treprostinil) vial	***Eligibility Criteria for all agents in the class** Approval will be granted for a diagnosis of pulmonary hypertension. Non-preferred products will be approved for members who have failed treatment with a Preferred Product. (Failure is defined as: lack of efficacy, allergy, intolerable side effects, contraindication to IV therapy or significant drug-drug interaction)

*VENTAVIS (iloprost) inhalation solution	Treprostinil (generic Remodulin) vial TYVASO (treprostinil) inhalation solution UPTRAVI (selexipag) tablet VELETRI (epoprostenol) vial	**Grandfathering:** Members who have been previously stabilized on a non-preferred product can receive approval to continue on the medication.
Guanylate Cyclase (sGC) Stimulator		
	PA Required ADEMPAS (riociguat) tablet	**Adempas** will be approved for patients who meet the following criteria: ● Patient is not a pregnant female and is able to receive monthly pregnancy tests while taking Adempas and one month after stopping therapy. AND ● Women of childbearing potential and their male partners must use one of the following contraceptive methods during treatment and one month after stopping treatment (e.g. IUD, contraceptive implants, tubal sterilization, a hormone method with a barrier method, two barrier methods, vasectomy with a hormone method, or vasectomy with a barrier method). AND ● Patient is not receiving dialysis or has severe renal failure (e.g. CrCl < 15 ml/min). AND ● Patient does not have severe liver impairment (e.g. Child Pugh C). AND ● Prescriber must be enrolled with the Adempas REMS Program. AND ● Female patients, regardless of reproductive potential, must be enrolled in the Adempas REMS program prior to starting therapy. AND ● Patient has a diagnosis of persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH) (WHO Group 4) after surgical treatment or has inoperable CTEPH OR ● Patient has a diagnosis of pulmonary hypertension and has failed treatment with a preferred product for pulmonary hypertension. (Failure is defined as a lack of efficacy, allergy, intolerable side effects, or significant drug-drug interactions).
Therapeutic Drug Class: **LIPOTROPICS** - *Effective 4/1/2020*		
No PA Required Colesevelam tablet Colestipol tablet Cholestyramine packet, light packet Ezetimibe tablet Fenofibrate capsule, tablet (generic Lofibra/Tricor)	**PA Required** ANTARA (fenofibrate) Colesevelam packet COLESTID (colestipol) tablet, granules Colestipol granules Fenofibric acid DR capsule Fenofibric acid tablet	Non-preferred bile acid sequestrates may be approved if the member has failed treatment with 2 preferred products in the last 12 months (failure is defined as lack of efficacy with 4 week trial, allergy, intolerable side effects or significant drug-drug interactions). Non-preferred fibrates may be approved if the member has failed treatment with generic gemfibrozil or generic fenofibrate and niacin ER in the last 12 months (failure is defined as lack of efficacy with 4 week trial of each drug, allergy, intolerable side effects or significant drug-drug interactions). Non-preferred lipotropic agents with a preferred product with same strength, dosage form, and active ingredient will be approved with adequate trial and/or failure of the preferred product with the same ingredient (such as preferred ezetimibe and Zetia) and 2 additional

Gemfibrozil tablet Niacin ER tablet *Omega-3 ethyl esters capsule (generic Lovaza)	Icosapent ethyl capsule LOPID (gemfibrozil) tablet LOVAZA (omega-3 ethyl esters) capsule PREVALITE (cholestyramine/aspartame) packet QUESTRAN (cholestyramine/sugar) packet NEXLETOL (bempedoic acid) NEXLIZET (bempedoic acid/ezetimibe) NIASPAN ER (niacin ER) TRIGLIDE (fenofibrate) TRILIPIX (fenofibric acid) VASCEPA (icosapent ethyl) capsule WELCHOL (colesevalam) tablet, packet ZETIA (ezetimibe) tablet	agents. (Failure is defined as: lack of efficacy with 4 week trial, allergy, intolerable side effects or significant drug-drug interactions). *__Omega-3 ethyl esters__ (generic Lovaza) may be approved for members who have a baseline triglyceride level ≥ 500 mg/dL **Lovaza** (brand name) may be approved if meeting the following: • Member has a baseline triglyceride level ≥ 500 mg/dl AND • Member has failed an adequate trial of omega-3 Ethyl Esters AND an adequate trial of gemfibrozil or fenofibrate (failure is defined as lack of efficacy with 4 week trial, allergy, intolerable side effects or significant drug-drug interactions) **Vascepa** (icosapent ethyl) may be approved if meeting the following: • Member has a baseline triglyceride level > 500 mg/dl AND • Member has failed an adequate trial of generic omega-3 ethyl esters AND an adequate trial of gemfibrozil or fenofibrate (failure is defined as lack of efficacy with 4 week trial, allergy, intolerable side effects or significant drug-drug interactions) OR • Vascepa (icosapent ethyl) is being prescribed to reduce CV risk for members on maximally tolerated statin therapy with triglyceride levels ≥ 150mg/dL and LDL-C levels between 41-100 mg/dL AND member meets one of the following: o Member is ≥ 45 years of age and has established atherosclerotic CV disease (e.g. coronary artery disease, cerebrovascular/carotid disease, peripheral arterial disease) OR o Member is ≥ 50 years of age with diabetes mellitus and has one or more of the following additional risk factors for CV disease: ▪ Male ≥ 55 years of age or female ≥ 65 years of age ▪ Cigarette smoker ▪ Hypertension ▪ HDL-C ≤ 40 mg/dL for men or ≤ 50 mg/dL for women ▪ hsCRP >3.00 mg/L (0.3 mg/dL) ▪ CrCl 30 to 59 mL/min ▪ Retinopathy ▪ Micro- or macroalbuminuria ▪ ABI <0.9 without symptoms of intermittent claudication Maximum Dose: Vascepa (icosapent ethyl) 4g daily
Therapeutic Drug Class: **STATINS** -*Effective 4/1/2020*		
No PA Required	**PA Required**	
Atorvastatin tablet Lovastatin tablet Pravastatin tablet	ALTOPREV (lovastatin ER) tablet CRESTOR (rosuvastatin) tablet	Non-preferred Statins may be approved following trial and failure of treatment with two preferred products (failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions).

Rosuvastatin tablet Simvastatin tablet	EZALLOR (rosuvastatin) sprinkle capsule Fluvastatin capsule LESCOL XL (fluvastatin ER) tablet LIPITOR (atorvastatin) tablet LIVALO (pitavastatin) tablet PRAVACHOL (pravastatin) tablet ZOCOR (simvastatin) tablet	Age Limitations: Altoprev will not be approved for members < 18 years of age. Fluvastatin and lovastatin will not be approved for members < 10 years of age. Livalo will not be approved for members < 6 years of age.
Therapeutic Drug Class: **STATIN COMBINATIONS** -*Effective 4/1/2020*		
	PA Required Amlodipine /atorvastatin CADUET (amlodipine/atorvastatin) Ezetimibe/simvastatin VYTORIN (ezetimibe/simvastatin)	Non-preferred Statin combinations may be approved following trial and failure of treatment with two preferred products (failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions). Children: Vytorin will not be approved for members < 18 years of age. Caduet will not be approved for members < 10 years of age.

IV. Central Nervous System

Therapeutic Drug Class: **ANTICONVULSANTS -Oral**-*Effective 10/1/2020*		
No PA Required Carbamazepine IR tablet, ER tablet, chewable, ER capsule Clobazam tablet Clonazepam tablet, ODT Divalproex capsule, DR tablet, ER tablet DILANTIN[BNR] (phenytoin) 30 mg capsules Ethosuximide capsule, solution	**PA Required** ***Non-preferred brand name medications do not require a prior authorization when the equivalent generic is preferred and "dispense as written" is indicated on the prescription.*** APTIOM (eslicarbazepine) BANZEL (rufinamide) BRIVIACT (brivaracetam) CARBATROL ER (carbamazepine)	Prior Authorization for members currently stabilized (in outpatient or acute care settings) on any non-preferred medication will be approved. Non-preferred brand name medications do not require a prior authorization when the equivalent generic is preferred and "dispense as written" is indicated on the prescription. <u>Non-Preferred Products Newly Started for Treating Seizure Disorder or Convulsions:</u> ● Non-preferred medications newly started for members with a diagnosis of seizure disorder/convulsions may be approved if meeting the following criteria: o The medication is being prescribed by a neurologist **OR** o The medication is in consultation with a neurologist and meets the following: ▪ The prescription meets minimum age and maximum dose limits listed in Table 1 **AND**

FELBATOL[BNR] (felbamate) tablet, suspension Lamotrigine tablet, chewable/disperse tabs Levetiracetam IR, ER tablet, solution Oxcarbazepine tablet, suspension Phenobarbital elixir, soln, tab PHENYTEK[BNR] (phenytoin ER) Phenytoin suspension, chewable, ER capsule Primidone tablet TEGRETOL [BNR] (carbamazepine) suspension Topiramate tablet, sprinkle cap Valproic acid capsule, solution Zonisamide capsule	Carbamazepine suspension CELONTIN (methsuximide) DEPAKOTE (divalproex DR) DIACOMIT (stiripentol) capsule DILANTIN (phenytoin ER) suspension, infatab, 100 mg capsules EPIDIOLEX (cannabidiol) EQUETRO (carbamazepine) Felbamate tablet, suspension FINTEPLA (fenfluramine) FYCOMPA (perampanel) GABITRIL (tiagabine) KEPPRA (levetiracetam) IR tablet, XR tablet, solution KLONOPIN (clonazepam) LAMICTAL (lamotrigine) Lamotrigine ODT, ER tablet MYSOLINE (primidone) ONFI (clobazam) OXTELLAR XR (oxcarbazepine) tablet PEGANONE (ethotoin) QUDEXY XR capsule Rufinamide suspension SABRIL (vigabatrin) powder packet, tablet	▪ For medications indicated for use as adjunctive therapy, the medication is being used in conjunction with another anticonvulsant medication **AND** o The prescription meets additional criteria listed for any of the following: **SYMPAZAN** (clobazam) film: o Member has history of trial and failure‡ of clobazam tablet or solution **OR** o Provider attests that member cannot take clobazam tablet or solution **EPIDIOLEX** (cannabidiol): o Member has diagnosis of seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet Syndrome **OR** o Member is ≥1 year of age and has a diagnosis of seizures associated with tuberous sclerosis complex (TSC). **BRIVIACT** (brivaracetam): o Member is ≥ 4 years of age **AND** o Member has history of trial and failure‡ of any levetiracetam-containing product. **APTIOM** (eslicarbazepine): o Member has history of trial and failure‡ of any carbamazepine-containing product. **DIACOMIT** (stiripentol): o Member is concomitantly taking clobazam **AND** o Member has diagnosis of seizures associated with Dravet syndrome. **FINTEPLA** (fenfluramine): o Member is ≥2 years of age AND has a diagnosis of seizures associated with Dravet syndrome. **ONFI (clobazam) suspension**: o Member is ≥2 years of age **AND** o Member has diagnosis of seizures associated with Lennox-Gastaut syndrome (LGS) **AND** o Member has documented swallowing difficulty due to young age and/or a medical condition, and is unable to use preferred tablet and capsule formulations **AND** o Member is not taking a concomitant opioid (or concomitant opioid therapy has been determined to be clinically appropriate due to inadequacy of alternative treatment options).

SPRITAM tablet

SYMPAZAN (clobazam)

TEGRETOL (carbamazepine) IR tablet, XR tablet, capsule, chewable

Tiagabine tablet

TOPAMAX tablet, sprinkle cap

Topiramate ER capsule

TRILEPTAL tablet, suspension

TROKENDI XR capsule

Vigadrone powder packet

Vigabatrin tablet

VIMPAT (lacosamide)

XCOPRI (cenobamate)

ZARONTIN (ethosuximide)

ZONEGRAN (zonisamide)

Non-Preferred Products Newly Started for Non-Seizure Disorder Diagnoses:

- Non-preferred medications newly started for non-seizure disorder diagnoses may be approved if meeting the following criteria:
  - Member has history of trial and failure‡ of two preferred agents AND
  - The prescription meets minimum age and maximum dose limits listed in Table 1.

‡Failure is defined as lack of efficacy, allergy, intolerable side effects, significant drug-drug interaction, or documented contraindication to therapy, or inability to take preferred formulation. Members identified as HLA-B*15:02 positive, carbamazepine and oxcarbazepine should be avoided per Clinical Pharmacogenetics Implementation Consortium Guideline. This may be considered a trial for prior authorization approvals of a non-preferred agent.

Table 1: Anticonvulsant Product Table

	Minimum Age**	**Maximum Dose****
Brivaracetam (BRIVIACT)	4 years	200 mg per day
Cannabidiol (EPIDIOLEX)	2 years	20 mg/kg/day
Carbamazepine (EPITOL)		1600 mg per day
Carbamazepine, all *except* suspension (TEGRETOL)		Not listed
Carbamazepine ER (CARBATROL)		1600 mg per day
Carbamazepine ER (EQUETRO)		1600 mg per day
Carbamazepine ER (TEGRETOL XR)		Not listed
Clobazam (ONFI)	1 year	40 mg per day
Clobazam film (SYMPAZAN)	2 years	40 mg per day
Clobazam suspension	1 year	40 mg per day
Clonazepam (KLONOPIN)		
Divalproex DR	10 years	
Divalproex DR (DEPAKOTE)	10 years	
Divalproex DR (DEPAKOTE SPRINKLE)	10 years	
Divalproex ER (DEPAKOTE ER)	10 years	
Eslicarbazepine (APTIOM)	4 years	1600 mg per day
Ethosuximide (ZARONTIN)		Not listed
Ethotoin (PEGANONE)		3000 mg per day
Felbamate	18 years	
Lacosamide (VIMPAT)	4 years	400 mg per day
Lamotrigine (LAMICTAL)	2 years	400 mg per day
Lamotrigine (LAMICTAL ODT)	2 years	400 mg per day
Lamotrigine ER (LAMICTAL XR)	13 years	600 mg per day
Levetiracetam (KEPPRA)	1 month	3000 mg per day

		Levetiracetam (SPRITAM)	4 years	3000 mg per day
		Levetiracetam ER (KEPPRA XR)	12 years	3000 mg per day
		Methsuximide (CELONTIN)		Not listed
		Oxcarbazepine (TRILEPTAL)		Not listed
		Oxcarbazepine ER (OXTELLAR XR)		Not listed
		Perampanel (FYCOMPA)	4 years	12 mg per day
		Phenytoin ER (DILANTIN)		1000 mg loading dose 600 mg maintenance dose
		Primidone (MYSOLINE)		2000 mg per day
		Rufinamide (BANZEL)	1 year	3200 mg per day
		Stiripentol (DIACOMIT)	2 years	50mg/kg/day
		Tiagabine	12 years	64 mg per day
		Tiagabine (GABITRIL)	12 years	64 mg per day
		Topiramate (TOPAMAX)		400 mg per day
		Topiramate ER (QUDEXY XR)	2 years	400 mg per day
		Topiramate ER (TROKENDI XR)	6 years	400 mg per day
		Valproic acid, including solution	10 years	
		Valproic acid (DEPAKENE)	10 years	
		Vigabatrin	1 month	3000 mg per day
		Vigabatrin (SABRIL)	1 month	3000 mg per day
		Zonisamide (ZONEGRAN)	16 years	600 mg per day
		**Limits based on data from FDA package insert. Approval for age/dosing that falls outside of the indicated range may be evaluated on a case-by-case basis.		

Therapeutic Drug Class: **NEWER GENERATION ANTI-DEPRESSANTS** -*Effective 1/1/2021*		
No PA Required	**PA Required**	
Bupropion IR, SR, XL Citalopram tablet, solution Desvenlafaxine succ ER tablet Duloxetine (generic Cymbalta) capsule Escitalopram tablet Fluoxetine capsules, solution Fluvoxamine tablet Mirtazapine tablet, ODT Paroxetine IR tablet	***Non-preferred brand name medications do not require a prior authorization when the equivalent generic is preferred and "dispense as written" is indicated on the prescription.*** APLENZIN ER (bupropion ER) tablet Bupropion XL (generic Forfivo XL) tablet CELEXA (citalopram) tablet CYMBALTA (duloxetine) capsule Desvenlafaxine fumarate ER tablet Duloxetine (generic Irenka) capsule	Prior authorization for Fetzima, Trintellix, or Viibryd will be approved for members who have failed an adequate trial with four preferred newer generation anti-depressant products (failure is defined as lack of efficacy with 6-week trial, allergy, intolerable side effects, or significant drug-drug interaction). All non-preferred products not listed above will be approved for members who have failed adequate trial with three preferred newer generation anti-depressant products. If three preferred newer generation anti-depressant products are not available for indication being treated, approval of prior authorization for non-preferred products will require adequate trial of all preferred products FDA approved for that indication (failure is defined as lack of efficacy with 6-week trial, allergy, intolerable side effects, or significant drug-drug interaction). **Citalopram** doses higher than 40mg/day for ≤60 years of age and 20mg for >60 years of age will require prior authorization. Please see the FDA guidance at: https://www.fda.gov/drugs/drugsafety/ucm297391.htm for important safety information.

Sertraline tablet, solution Trazodone tablet Venlafaxine IR tablet Venlafaxine ER capsules	EFFEXOR XR (venlafaxine ER) capsule Escitalopram solution FETZIMA (levomilnacipran ER) capsule Fluoxetine IR tablet, fluoxetine DR capsule Fluvoxamine ER capsule FORFIVO XL (bupropion ER) tablet LEXAPRO (escitalopram) tablet Nefazodone tablet Paroxetine ER tablet PAXIL (paroxetine) tablet, suspension PAXIL CR (paroxetine ER) tablet PEXEVA (paroxetine) tablet PRISTIQ ER (desvenlafaxine succ ER) tablet PROZAC (fluoxetine) pulvule REMERON (mirtazapine) tablet, soltab (ODT) SARAFEM (fluoxetine) tablet TRINTELLIX (vortioxetine) tablet Venlafaxine ER tablets VIIBRYD (vilazodone) tablet WELLBUTRIN SR, XL (bupropion) tablet ZOLOFT (sertraline) tablet, solution	**Grandfathering:** Members currently stabilized on a Non-preferred newer generation antidepressant can receive approval to continue on that agent for one year if medically necessary. **Verification may be provided from the prescriber or the pharmacy.**

<table>
<tr><td colspan="3">Therapeutic Drug Class: MONOAMINE OXIDASE INHIBITORS (MAOis) -Effective 1/1/2021</td></tr>
<tr><td></td><td>PA Required

EMSAM (selegiline) patch

MARPLAN (isocarboxazid) tablet

NARDIL (phenelzine) tablet

PARNATE (tranylcypromine) tablet

Phenelzine tablet

Tranylcypromine tablet</td><td>Non-preferred products will be approved for members who have failed adequate trial (8 weeks) with three preferred anti-depressant products. If three preferred anti-depressant products are not available for indication being treated, approval of prior authorization for non-preferred products will require adequate trial of all preferred anti-depressant products FDA approved for that indication. (Failure is defined as: lack of efficacy after 8-week trial, allergy, intolerable side effects, or significant drug-drug interaction)

Grandfathering: Members currently stabilized on a Non-preferred MAOi antidepressant can receive approval to continue on that agent for one year if medically necessary. Verification may be provided from the prescriber or the pharmacy.</td></tr>
<tr><td colspan="3">Therapeutic Drug Class: TRICYCLIC ANTI-DEPRESSANTS (TCAs) -Effective 1/1/2021</td></tr>
<tr><td>No PA Required

Amitriptyline tablet

Doxepin 10mg, 25mg, 50mg, 75mg, 100mg, 150mg capsule

Doxepin solution

Imipramine HCl tablet

Nortriptyline capsule, solution</td><td>PA Required

Non-preferred brand name medications do not require a prior authorization when the equivalent generic is preferred and “dispense as written” is indicated on the prescription.

Amoxapine tablet

ANAFRANIL (clomipramine) capsule

Clomipramine capsule

Desipramine tablet

Imipramine pamoate capsule

Maprotiline tablet

NORPRAMIN (desipramine) tablet

PAMELOR (nortriptyline) capsule

Protriptyline tablet

SURMONTIL (trimipramine) capsule

TOFRANIL (imipramine HCl)

Trimipramine capsule</td><td>Non-preferred products will be approved for members who have failed adequate trial (8 weeks) with three preferred tricyclic products. If three preferred products are not available for indication being treated, approval of prior authorization for non-preferred products will require adequate trial of all tricyclic preferred products FDA approved for that indication. (Failure is defined as: lack of efficacy after 8-week trial, allergy, intolerable side effects, or significant drug-drug interaction)

Grandfathering: Members currently stabilized on a Non-preferred TCA antidepressant can receive approval to continue on that agent for one year if medically necessary. Verification may be provided from the prescriber or the pharmacy.

Silenor (doxepin 3mg, 6mg) approval criteria can be found on the Appendix P</td></tr>
</table>

Therapeutic Drug Class: **ANTI-PARKINSON'S AGENTS** -*Effective 4/1/2020*		
Dopa decarboxylase inhibitors, dopamine precursors and combinations		
No PA Required Carbidopa/Levodopa IR, ER tablet	**PA Required** Carbidopa tablet Carbidopa/Levodopa ODT DUOPA (carbidopa/levodopa) Suspension INBRIJA (levodopa) capsule for inhalation RYTARY ER (carbidopa/levodopa) capsule SINEMET (carbidopa/levodopa) IR, ER tablet STALEVO (carbidopa/levodopa/ entacapone) tablet	Non-preferred agents may be approved with adequate trial and failure of carbidopa-levodopa IR and ER formulations (failure is defined as lack of efficacy with a 4-week trial, allergy, intolerable side effects or significant drug-drug interactions). Carbidopa or levodopa single agent products may be approved for members with diagnosis of Parkinson's Disease as add-on therapy to carbidopa-levodopa. Non-preferred medications that <u>are not</u> prescribed for Parkinson's Disease (or an indication related to Parkinson's Disease) may receive approval without meeting trial and failure step therapy criteria. Members with history of trial and failure of a non-preferred Parkinson's Disease agent that is the brand/generic equivalent of a preferred product (same strength, dosage form and active ingredient) may be considered as having met a trial and failure of the equivalent preferred. <u>Grandfathering</u>: Members currently stabilized on a non-preferred product may receive approval to continue therapy with that product.
MAO-B inhibitors		
No PA Required Selegiline capsule Selegiline tablet	**PA Required** AZILECT (Rasagiline) tablet Rasagiline tablet XADAGO (safinamide) tablet ZELAPAR (selegiline) ODT	Non-preferred agents may be approved with adequate trial and failure of selegiline capsule or tablet (failure is defined as lack of efficacy with a 4-week trial, allergy, intolerable side effects or significant drug-drug interactions). Non-preferred medications that <u>are not</u> prescribed for Parkinson's Disease (or an indication related to Parkinson's Disease) may receive approval without meeting trial and failure step therapy criteria. Members with history of trial and failure of a non-preferred Parkinson's Disease agent that is the brand/generic equivalent of a preferred product (same strength, dosage form and active ingredient) may be considered as having met a trial and failure of the equivalent preferred. <u>Grandfathering</u>: Members currently stabilized on a non-preferred product may receive approval to continue therapy with that product.
Dopamine Agonists		
No PA Required Pramipexole IR tablet Ropinirole IR tablet	**PA Required** Bromocriptine capsule, tablet CYCLOSET (bromocriptine) tablet	Non-preferred agents may be approved with adequate trial and failure of ropinirole IR AND pramipexole IR (failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions).

	MIRAPEX (pramipexole) IR, ER tablet NEUPRO (rotigotine) patch PARLODEL (bromocriptine) Pramipexole ER tablet REQUIP (ropinirole) tablet, XR tablet Ropinirole ER tablet	Non-preferred medications that <u>are not</u> prescribed for Parkinson's Disease (or an indication related to Parkinson's Disease) may receive approval without meeting trial and failure step therapy criteria. Members with history of trial and failure of a non-preferred Parkinson's Disease agent that is the brand/generic equivalent of a preferred product (same strength, dosage form and active ingredient) may be considered as having met a trial and failure of the equivalent preferred. <u>Grandfathering</u>: Members currently stabilized on a non-preferred product may receive approval to continue therapy with that product.
Other Parkinson's agents		
No PA Required Amantadine cap, tab, syrup Benztropine tablet Trihexyphenidyl tab, elixir	**PA Required** COMTAN (entacapone) tablet Entacapone tablet GOCOVRI (amantadine) capsule NOURIANZ (istradefylline) tablet OSMOLEX ER (amantadine) tab TASMAR (tolcapone) tablet Tolcapone tablet	Non-preferred agents may be approved with adequate trial and failure of two preferred agents (failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions). Non-preferred medications that <u>are not</u> prescribed for Parkinson's Disease (or an indication related to Parkinson's Disease) may receive approval without meeting trial and failure step therapy criteria. Members with history of trial and failure of a non-preferred Parkinson's Disease agent that is the brand/generic equivalent of a preferred product (same strength, dosage form and active ingredient) may be considered as having met a trial and failure of the equivalent preferred. <u>Grandfathering</u>: Members currently stabilized on a non-preferred product may receive approval to continue therapy with that product.
Therapeutic Drug Class: **ATYPICAL ANTI-PSYCHOTICS - Oral** - *Effective 4/1/2020*		
No PA Required* **For injectable Atypical Antipsychotics please see Appendix P for criteria** Aripiprazole tablet Clozapine tablet LATUDA (lurasidone) **2nd line**** Olanzapine tablet, ODT Quetiapine IR tablet*** Quetiapine ER tablet Risperidone tablet, oral soln, ODT	**PA Required** ***Non-preferred brand name medications do not require a prior authorization when the equivalent generic is preferred and "dispense as written" is indicated on the prescription.*** ABILIFY (aripiprazole) tablet, oral soln, ODT, MyCite Aripiprazole oral solution****, ODT CAPLYTA (lumateperone) CLOZARIL (clozapine) Clozapine ODT	Non-preferred products may be approved for members meeting all of the following: • Medication is being prescribed for an FDA-Approved indication (Table 1) AND • Prescription meets dose and age limitations (Table 3) AND • Member has history of trial and failure of three preferred products (failure defined as lack of efficacy with 6-week trial, allergy, intolerable side effects, significant drug-drug interactions, or known interacting genetic polymorphism that prevents safe preferred product dosing) *<u>Age Limits</u>: All products including preferred products will require a PA for members younger than the FDA approved age for the agent (Table 3). Members younger than the FDA approved age for the agent who are currently stabilized on an atypical antipsychotic will be eligible for grandfathering. **Atypical Antipsychotic prescriptions for members under 5 years of age may require a provider-provider telephone consult with a child and adolescent psychiatrist (provided at no cost to provider or member).** **Latuda (lurasidone)** may be approved for the treatment of schizophrenia or bipolar depression if the member has tried and failed treatment with one preferred product (qualifying diagnosis verified by AutoPA).

Ziprasidone	GEODON (ziprasidone) FANAPT (iloperidone) FAZACLO (clozapine ODT) Iloperidone INVEGA (paliperidone) olanzapine/fluoxetine NUPLAZID (pimavanserin) Paliperidone REXULTI (brexpiprazole) RISPERDAL (risperidone) tablet, M-tab (ODT), oral solution SAPHRIS (asenapine) SEROQUEL IR (quetiapine IR)*** SEROQUEL XR (quetiapine ER)*** SYMBYAX (olanzapine/fluoxetine) VERSACLOZ (clozapine suspension) VRAYLAR (cariprazine) ZYPREXA (olanzapine) ZYPREXA ZYDIS (olanzapine ODT)	***__Quetiapine IR__ when given at sub-therapeutic doses may be restricted for therapy. Low-dose quetiapine (<150mg/day) is only FDA approved as part of a drug titration schedule to aid patients in getting to the target quetiapine dose. PA will be required for quetiapine < 150mg per day except for utilization (when appropriate) in members 65 years or older. PA will be approved for members 10-17 years of age with approved diagnosis (Table 3) stabilized on <150mg quetiapine IR per day. ****__Aripiprazole solution__: Aripiprazole <u>tablet</u> quantity limit is 2 tablets/day for pediatric members to allow for incremental dose titration and use of the preferred tablet formulation should be considered for dose titrations when possible and clinically appropriate. If incremental dose cannot be achieved with titration of the aripiprazole tablet for members < 18 years of age OR for members unable to swallow solid tablet dosage form, aripiprazole solution may be approved. For all other cases, aripiprazole solution is subject to meeting non-preferred product approval criteria listed above. **Nuplazid (pimavanserin tartrate)** may be approved for the treatment of hallucinations and delusions associated with Parkinson's Disease psychosis AND following trial and failure of therapy with quetiapine or clozapine (failure will be defined as intolerable side effects, drug-drug interaction, or lack of efficacy). **Abilify MyCite** may be approved if meeting all of the following: • Member has history of adequate trial and failure of 5 preferred agents (one trial must include aripiprazole tablet). Failure is defined as lack of efficacy with 6-week trial on maximally tolerated dose, allergy, intolerable side effects, significant drug-drug interactions AND • Information is provided regarding adherence measures being recommended by provider and followed by member (such as medication organizer or digital medication reminders) AND • Member has history of adequate trial and failure of 3 long-acting injectable formulations of atypical antipsychotics, one of which must contain aripiprazole (failure is defined as lack of efficacy with 8-week trial, allergy, intolerable side effects, significant drug-drug interactions) AND • Abilify MyCite is being used with a MyCite patch and member is using a compatible mobile application. AND • Medication adherence information is being shared with their provider via a web portal or dashboard. <u>Quantity Limits</u>: Quantity limits will be applied to all products (Table 2). In order to receive approval for off-label dosing, the member must have an FDA approved indication and must have tried and failed on the FDA approved dosing regimen. <u>Grandfathering</u>: Members currently stabilized on a non-preferred atypical antipsychotic or Latuda can receive approval to continue therapy with that agent for one year.

Table 1: Approved Indications

Drug	Indication
Abilify (aripiprazole)	• Schizophrenia • Acute treatment of manic or mixed episodes associated with bipolar I disorder • Adjunctive treatment of major depressive disorder • Irritability associated with autistic disorder • Treatment of Tourette's Disorder
Caplyta (lumateperone)	• Schizophrenia
Fanapt (iloperidone)	• Acute treatment of schizophrenia in adults
Fazaclo, Versacloz (clozapine)	• Treatment-resistant schizophrenia • Reducing the risk of recurrent suicidal behavior in patients with schizophrenia or schizoaffective disorder
Geodon (ziprasidone)	• Schizophrenia • Bipolar I disorder (acute mixed or manic episodes and maintenance treatment as adjunct to lithium or valproate) • Acute treatment of agitation in schizophrenia
Latuda (lurasidone)	• Schizophrenia • Bipolar I disorder
Nuplazid (pimavanserin)	• hallucinations and delusions associated with Parkinson's disease psychosis
Invega (paliperidone)	• Schizophrenia • Schizoaffective disorder
Risperdal (risperidone)	• Schizophrenia • Bipolar mania • Irritability associated with autistic disorder
Rexulti (brexpiprazole)	• Adjunctive therapy to antidepressants for the treatment of major depressive disorder • Schizophrenia
Saphris (asenapine)	• Acute and maintenance of schizophrenia • Bipolar mania, monotherapy • Maintenance treatment of bipolar I disorder as an adjunct to lithium or divalproex
Seroquel (quetiapine) Seroquel XR (quetiapine ER)	• Treatment of schizophrenia • Acute treatment of manic or mixed episodes associated with bipolar I disorder, as monotherapy or as an adjunct to lithium or divalproex • Maintenance treatment of bipolar I disorder as an adjunct to lithium or divalproex • Adjunctive treatment of major depressive disorder (Seroquel XR only)
Symbyax (olanzapine/fluoxetine)	• Treatment resistant depression • Bipolar I disorder
Vraylar (cariprazine)	• Schizophrenia • Bipolar (acute treatment)
Zyprexa (olanzapine)	• Schizophrenia • Bipolar I disorder

Table 2: Quantity Limits

Brand Name	Generic Name	Quantity Limits
Abilify	Aripiprazole	Maximum one tablet per day (maximum of two tablets per day allowable for members < 18 years of age to accommodate for incremental dose changes)
Caplyta	Lumateperone	Maximum dosage of 42mg per day

Clozaril	Clozapine	Maximum dosage of 900mg per day
Fazaclo	Clozapine	Maximum dosage of 900mg per day
Fanapt	Iloperidone	Maximum two tablets per day
Geodon	Ziprasidone	Maximum two capsules per day
Invega	Paliperidone	Maximum one capsule per day
Latuda	Lurasidone	Maximum one tablet per day (If dosing 160mg for schizophrenia, then max of two tablets per day)
Nuplazid	Pimavanserin	Maximum dosage of 34mg per day
Risperdal	Risperidone	Maximum dosage of 12mg/day
Rexulti	Brexpiprazole	Maximum of 3mg/day for MDD adjunctive therapy, Maximum of 4mg/day for schizophrenia
Saphris	Asenapine	Maximum two tablets per day
Secuado	Asenapine	Maximum 1 patch per day
Seroquel	Quetiapine	Maximum three tablets per day
Seroquel XR	Quetiapine ER	Maximum one tablet per day (for 300mg & 400mg tablets max 2 tablets per day)
Symbyax	Olanzapine/ fluoxetine	Maximum three capsules per day (18mg olanzapine/75mg fluoxetine)
Vraylar	Cariprazine	Maximum dosage of 6mg/day
Zyprexa	Olanzapine	Maximum one tablet per day
Zyprexa Zydis	Olanzapine ODT	Maximum one tablet per day

Table 3: FDA Approved Pediatric Dosing by Age

Drug	FDA Approved Indication	FDA-Approved Age	Max FDA-Approved Dose
Asenapine (Saphris, Secuado)	APPROVED FOR ADULTS ONLY		
Brexpiprazole (Rexulti)			
Cariprazine (Vraylar)			
Clozapine (Fazaclo, Clozaril)			
Iloperidone (Fanapt)			
Lumateperone (Caplyta)			
Pimavanserin (Nuplazid)			
Quetiapine ER (Seroquel XR)			
Ziprasidone (Geodon)			
Aripiprazole (Abilify)	Autism/Psychomotor Agitation Bipolar Disorder/Mixed Mania Schizophrenia Gilles de la Tourette's Syndrome	6-17 years 10-17 years 13-17 years 6-17 years	15mg/day 30mgday 30mg/day 20mg/day

Lurasidone (Latuda)	Schizophrenia Bipolar Depression	13-17 years 10-17 years	80mg/day 80mg/day
Olanzapine (Zyprexa)	Schizophrenia	13-17 years	10mg/day
Olanzapine (Zyprexa Zydis)	Bipolar Disorder/Mixed Mania	13-17 years	10mg/day
Paliperidone (Invega ER)	Schizophrenia	12-17 years	12mg/day
Risperidone (Risperdal)	Autism/Psychomotor Agitation Bipolar Disorder/Mixed Mania Schizophrenia	5-16 years 10-17 years 13-17 years	3mg/day 6mg/day 6mg/day
Quetiapine Fumarate (Seroquel)	Schizophrenia Bipolar Disorder/Mixed Mania	13-17 years 10-17 years	800 mg/day 600 mg/day
Olanzapine/fluoxetine (Symbyax)	Bipolar I disorder	10-17 years	12mg/50mg/day

Therapeutic Drug Class: **CALCITONIN GENE – RELATED PEPTIDE INHIBITORS (CGRPis)** -*Effective 4/1/2020*

PA Required for all agents

*AIMOVIG (erenumab) autoinjector	AJOVY (fremanezumab) syringe
*EMGALITY 120mg (galcanezumab) pen, syringe	EMGALITY 100mg (galcanezumab) syringe
	NURTEC (rimegepant) ODT
	UBRELVY (ubrogepant) tablet

***Emgality 120mg** (galcanezumab) or **Aimovig** (erenumab) may be approved for members meeting Migraine Prevention Prior Authorization Criteria below.

Migraine Prevention Prior Authorization Criteria (must meet all of the following):

- Member is 18 years of age or older AND
- Member is in need of prevention of episodic or chronic migraine AND
- Member has diagnosis of migraine with or without aura AND
- Member has tried and failed 2 oral preventative pharmacological agents listed as Level A per American Headache Society/American Academy of Neurology (i.e. divalproex, topiramate, metoprolol, propranolol). Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction AND
- Headache count: If prescribed for episodic migraine member has history of 4-14 migraine days per month OR if prescribed for chronic migraine member has history of 15 or more headache days per month where 8 or more were migraine days for three or more months AND
- Member does not have history of MI, stroke, TIA, unstable angina, coronary artery bypass surgery, or other revascularization procedures within previous 12 months AND
- Prescription meets one of the following:
  - Medication is not prescribed for chronic migraine with medication overuse headache OR
  - Member is prescribed Aimovig for chronic migraine with medication overuse headache resulting from taking triptans ≥ 10 days/month, non-narcotic analgesics ≥ 15 days/month (such as acetaminophen, NSAID), or a combination of analgesics ≥ 10 days/month (including non-narcotic, ergot, opioid, butalbital) AND member has not been using a migraine prevention medication for 2 months prior to Aimovig prescription

AND

- Initial authorization will be limited to the following:

		○ For episodic migraine: Initial authorization will be for 6 months. Continuation (12-month authorization) will require documentation of clinically significant improvement after 4 months use (and documentation of number of migraine days per month) ○ For chronic migraine: Initial authorization will be for 4 months. Continuation (12-month authorization) will require documentation of clinically significant improvement after 3 months use (and documentation of number of migraine days per month) <u>Non-Preferred Medications for Migraine Prevention</u>: Non-preferred medications for migraine prevention may be approved if the member meets the Migraine Prevention Prior Authorization Criteria above AND the member has history of adequate trial and failure of Emgality 120mg AND Aimovig therapy (failure is defined as lack of efficacy with 4 week trial, allergy, intolerable side effects, or significant drug-drug interaction). Members taking a non-preferred agent for migraine prevention that have not shown clinically significant improvement for 4 months for acute episodic migraine treatment or 3 months for chronic migraine treatment will be allowed to transition to a preferred CGRP agent without meeting the "headache count" criteria listed above. <u>Non-Preferred Medications for Acute Migraine Treatment or Cluster Headache Treatment:</u> Non-preferred medications for acute migraine treatment (Ubrelvy) may be approved for members meeting all of the following: • Member is 18 years of age or older AND • Medication is being prescribed to treat migraine headache with moderate to severe pain AND • Member is not receiving an injectable form of CGRP medication for any indication AND • Member has history of trial and failure of all of the following (failure is defined as lack of efficacy with 4-week trial, contraindication, allergy, intolerable side effects, or significant drug-drug interaction): ○ Three triptans (including at least two different routes of administration) AND ○ Two NSAID agents AND ○ Dihydroergotamine vial or an ergotamine combination product Non-preferred medications for treatment of cluster headache (Emgality 100mg) may be approved for members meeting all of the following: • Member is 19-65 years of age AND • Member meets diagnostic criteria for episodic cluster headache (has had no more than 8 attacks per day, a minimum of one attack every other day, and at least 4 attacks during the week prior to this medication being prescribed) AND

		• Member is not taking other preventative medications to reduce the frequency of cluster headache attacks AND
		• Member has history of trial and failure of all of the following (failure is defined as lack of efficacy with 4-week trial, contraindication, allergy, intolerable side effects, or significant drug-drug interaction):
		  o Oxygen therapy AND
		  o Sumatriptan subcutaneous or intranasal AND
		  o Zolmitriptan intranasal AND
		• Member is not prescribed this medication for medication overuse headache AND
		• Member does not have ECG abnormalities compatible with acute cardiovascular event or conduction delay AND
		• Member does not have a history within the last 6 months of myocardial infarction, unstable angina, percutaneous coronary intervention, coronary artery bypass grafting, deep vein thrombosis, or pulmonary embolism AND
		• Member does not have a history of stroke, intracranial or carotid aneurysm, intracranial hemorrhage, or vasospastic angina, clinical evidence of peripheral vascular disease, or diagnosis of Raynaud's AND
		• Initial authorization will be limited to 8 weeks. Continuation (12-month authorization) will require documentation of clinically relevant improvement with no less than 30% reduction in headache frequency in a 4 week period.
		
		<u>Maximum Dosing:</u>
		Aimovig (erenumab): 140mg per 30 days
		Emgality 120mg (galcanezumab): 240mg once as first loading dose then 120mg monthly
		Emgality 100mg (galcanezumab): 300mg per 30 days
		Ajovy (fremanezumab): 225mg monthly or 675mg every three months
		Ubrelvy 50mg (ubrogepant): 16 tablets/30 days (800mg per 30 days)
		Ubrelvy 100mg (ubrogepant): 16 tablets/30 days (1600mg per 30 days)

Therapeutic Drug Class: **LITHIUM AGENTS** -*Effective 4/1/2020*		
No PA Required Lithium Carbonate capsule Lithium Carbonate tablet Lithium ER tablet	**PA Required** ***Non-preferred brand name medications do not require a prior authorization when the equivalent generic is preferred and "dispense as written" is indicated on the prescription.*** LithoBID ER (lithium ER) tablet Lithium Citrate soln	Non-preferred products may be approved with trial and failure of one preferred agent (failure is defined as lack of efficacy with 6-week trial, allergy, intolerable side effects, significant drug-drug interactions, intolerance to dosage form). Grandfathering: Members currently stabilized on a non-preferred product may receive approval to continue therapy with that product.

Therapeutic Drug Class: **NEUROCOGNITIVE DISORDER AGENTS** -*Effective 4/1/2020*		
***Must meet eligibility criteria** *Donepezil 5mg, 10mg tablet *Donepezil ODT *Memantine tablets *Rivastigmine capsule, patch	**PA Required** ARICEPT (donepezil) tablets (all strengths), ODT Donepezil 23mg tablet EXELON (rivastigmine) cap, patch, soln. Galantamine IR tablet, soln Galantamine ER capsule Memantine ER capsule, IR solution MESTINON (pyridostigmine) tab, syrup NAMENDA IR, XR (memantine) NAMZARIC (memantine/donepezil) RAZADYNE (galantamine) tab, oral soln RAZADYNE ER (galantamine) cap	***Eligibility criteria for Preferred Agents –** All preferred products may be approved without PA if the member has a diagnosis of neurocognitive disorder which can be verified by SMART PA. Non-preferred products may be approved if the member has failed treatment with one of the preferred products in the last 12 months. (Failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions) Members currently stabilized on a non-preferred product may receive approval to continue on that agent for one year if medically necessary and if there is a diagnosis of neurocognitive disorder.
Therapeutic Drug Class: **SEDATIVE HYPNOTICS** -*Effective 4/1/2020*		
Non-Benzodiazepines		
No PA Required* (unless age, dose, or duplication criteria apply) Eszopiclone tablet Zaleplon capsule Zolpidem IR tablet Zolpidem ER tablet	**PA Required** AMBIEN (zolpidem) tablet AMBIEN CR (zolpidem) tablet BELSOMRA (suvorexant) tablet DAYVIGO (lemoborexant) tablet EDLUAR (zolpidem) SL tablet INTERMEZZO (zolpidem) SL tablet LUNESTA (eszopiclone) tablet Ramelteon tablet	Non-preferred non-benzodiazepine sedative hypnotics may be approved for members who have failed treatment with two preferred non-benzodiazepine agents (failure is defined as lack of efficacy with a 2-week trial, allergy, intolerable side effects, or significant drug-drug interaction). <u>Children:</u> Prior authorization will be required for all agents for children < 18 years of age. <u>Duplications:</u> Only one agent in the sedative hypnotic drug class will be approved at a time (concomitant use of agents in the same sedative hypnotic class or differing classes will not be approved). All sedative hypnotics will require prior authorization for members ≥ 65 years of age when exceeding 90 days of therapy. **Belsomra** (suvorexant) may be approved for adult members that meet the following:

	ROZEREM (ramelteon) tablet SONATA (zaleplon) capsule Zolpidem SL tablet	• Members has trialed and failed therapy with two preferred agents (failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction) AND • Member is not receiving strong inhibitors (such as erythromycin, clarithromycin, telithromycin, itraconazole, ketoconazole, posaconazole, fluconazole, voriconazole, delavirdine, and milk thistle) or inducers (such as carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifampin, rifabutin, rifapentine, dexamethasone, efavirenz, etravirine, nevirapine, darunavir/ritonavir, ritonavir, and St John's Wort) of CYP3A4 AND • Member does not have a diagnosis of narcolepsy **Dayvigo** (lemborexant) may be approved for adult member that meet the following: • Member has trialed and failed therapy with two preferred agents AND Belsomra (surovexant). Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction AND • Member is not receiving strong inhibitors (such as erythromycin, clarithromycin, telithromycin, itraconazole, ketoconazole, posaconazole, fluconazole, voriconazole, delavirdine, and milk thistle) or inducers (such as carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifampin, rifabutin, rifapentine, dexamethasone, efavirenz, etravirine, nevirapine, darunavir/ritonavir, ritonavir, and St John's Wort) of CYP3A4 AND • Member does not have a diagnosis of narcolepsy **Rozerem** (ramelteon) may be approved for adult members with a history/concern of substance abuse or for documented concern of diversion within the household without failed treatment on a preferred agent Prior authorization will be required for prescribed doses exceeding maximum (Table 1).
Benzodiazepines		
No PA Required* (unless age, dose, or duplication criteria apply) Temazepam 15mg, 30mg capsule Triazolam tablet	**PA Required** Estazolam tablet Flurazepam capsule HALCION (triazolam) tablet RESTORIL (all strengths) capsule Temazepam 7.5mg, 22.5mg capsule	Non-preferred benzodiazepine sedative hypnotics may be approved for members who have trialed and failed therapy with two preferred benzodiazepine agents (failure is defined as lack of efficacy with a 2-week trial, allergy, intolerable side effects, or significant drug-drug interaction). **Temazepam 7.5mg and 22.5 mg** may be approved if the member has trialed and failed temazepam 15mg or 30mg AND one other preferred product (failure is defined as lack of efficacy with a 2 week trail, allergy, intolerable side effects, or significant drug-drug interaction). <u>Children:</u> Prior authorization will be required for all sedative hypnotic agents when prescribed for children < 18 years of age. <u>Duplications:</u> Only one agent in the sedative hypnotic drug class will be approved at a time (concomitant use of agents in the same sedative hypnotic class or differing classes will not be approved).

		All sedative hypnotics will require prior authorization for member's ≥ 65 years of age when exceeding 90 days of therapy. Grandfathering: Members currently stabilized on a non-preferred benzodiazepine medication may receive authorization to continue that medication. Prior authorization will be required for prescribed doses exceeding maximum (Table 1).

Table 1: Sedative Hypnotic Maximum Dosing

Brand	Generic	Maximum Dose
Non-Benzodiazepine		
Ambien CR	Zolpidem CR	12.5 mg/day
Ambien IR	Zolpidem IR	10 mg/day
Belsomra	Suvorexant	20 mg/day
Dayvigo	Lemborexant	10mg/day
Edluar	Zolpidem sublingual	Men: 10 mg/day Women: 5 mg/day
Intermezzo	Zolpidem sublingual	Men: 3.5mg/day Women: 1.75 mg/day
Lunesta	Eszopiclone	3 mg/day
Sonata	Zaleplon	20 mg/day
Rozerem	Ramelteon	8 mg/day
Zolpimist	Zolpidem spray	Men: 10 mg (2 sprays)/day Women: 5 mg (1 spray)/day
Benzodiazepine		
Halcion	Triazolam	0.5 mg/day
Restoril	Temazepam	30 mg/day
-	Estazolam	2 mg/day
-	Flurazepam	30 mg/day
-	Quazepam	15 mg/day

Therapeutic Drug Class: **SKELETAL MUSCLE RELAXANTS** -*Effective 7/1/2020*

No PA Required (if under 65 years of age) *	PA Required	
Baclofen (generic Lioresal) Cyclobenzaprine (generic Flexeril) 5mg and 10mg tablet Methocarbamol	AMRIX ER (cyclobenzaprine ER) Carisoprodol Chlorzoxazone Cyclobenzaprine 7.5mg tabs	All agents in this class will require a PA for members 65 years of age and older. The maximum allowable approval will be for a 7-day supply. Non-preferred skeletal muscle relaxants will be approved for members who have trialed and failed‡ three preferred agents. (Failure is defined as: lack of efficacy, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions.) Authorization for any **CARISOPRODOL** product will be given for a maximum 3-week one-time authorization for members with acute, painful musculoskeletal conditions who have failed treatment with three preferred products within the last 6 months.

Tizanidine tablet	Cyclobenzaprine ER capsule DANTRIUM (dantrolene) *Dantrolene FEXMID (cyclobenzaprine) LORZONE (chlorzoxazone) METAXALL (metaxalone) Metaxalone NORGESIC FORTE (orphenadrine/aspirin/caffeine) Orphenadrine ER ROBAXIN (methocarbamol) SKELAXIN (metaxalone) SOMA (carisoprodol) Tizanidine capsules ZANAFLEX (tizanidine)	*__Dantrolene__ will be approved for members 5-17 years of age who have trialed and failed‡ one preferred agent and meet the following criteria: ● Documentation of age-appropriate liver function tests AND ● One of following diagnoses: Multiple Sclerosis, Cerebral Palsy, stroke, upper motor neuron disorder, or spinal cord injury ● Dantrolene will be approved for the period of one year ● If a member is stabilized on dantrolene at <18 years of age, they may continue to receive approval after turning 18 years of age ● (Failure is defined as: lack of efficacy, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions.) ‡Failure is defined as: lack of efficacy with 14 day trial, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions.
Therapeutic Drug Class: **STIMULANTS AND RELATED AGENTS** -*Effective 10/1/2020*		
***No PA Required (if age, max daily dose, and diagnosis met)** ADDERALL XR (mixed amphetamine salts ER) [BNR] Armodafinil (generic Nuvigil) Atomoxetine (generic Strattera) Mixed-amphetamine salts (generic Adderall IR) CONCERTA (Methylphenidate ER) tablet [BNR]	**PA Required** ADDERALL (mixed-amphetamine salts IR) ADHANSIA XR (methylphenidate ER) capsule ADZENYS ER, XR-ODT (amphetamine) Mixed-Amphetamine salts ER (generic Adderall XR) APTENSIO XR (methylphenidate ER) Clonidine ER tablet	*Preferred medications may be approved through AutoPA for indications listed in Table 1 (preferred medications may also receive approval for off-label use for fatigue associated with multiple sclerosis). Non-preferred medications may be approved for members meeting the following criteria (for Sunosi (solriamfetol) and Wakix (pitolisant), refer to specific criteria listed below): ● Prescription meets indication/age limitation criteria (Table 1) **AND** ● Member meets one of the following: • If member is ≥ 6 years of age, has documented trial and failure‡ with three preferred products in the last 24 months **OR** • If members is 3 –5 years of age, has documented trial and failure‡ with one preferred product in the last 24 months **AND** ● For Daytrana, Methylin solution, Quillichew, Quillivant XR and Dyanavel XR:

Dexmethylphenidate IR (generic Focalin) FOCALIN XR [BNR] (dexmethylphenidate ER) Guanfacine ER Methylphenidate IR (generic Ritalin IR) Modafinil (generic Provigil) VYVANSE (lisdexamfetamine) capsules, chewables	COTEMPLA XR ODT (methylphenidate ER) Dextroamphetamine spansule, tablet DAYTRANA (methylphenidate) transdermal DESOXYN (methamphetamine) DEXEDRINE (dextroamphetamine) Dexmethylphenidate ER (generic Focalin XR) DYANAVEL XR solution (amphetamine) EVEKEO (amphetamine) FOCALIN IR (dexmethylphenidate) INTUNIV (guanfacine ER) JORNAY PM (methylphenidate) Methylphenidate ER (generic Adzenys ER, Aptensio XR, Concerta, Metadate CD/ER/LA, Relexxii) METHYLIN SUSPENSION (methylphenidate) MYDAYIS ER (dextroamphetamine/amphetamine) NUVIGIL (armodafinil) PROCENTRA (dextroamphetamine liquid) PROVIGIL (modafinil) QUILLICHEW (methylphenidate)	• One of the preferred trials must include Vyvanse chewable tablet, Focalin XR, Vyvanse capsules, or Adderall XR **AND** • Member has a documented difficulty swallowing and is unable to utilize alternative dosing with preferred tablet and capsule formulations. **SUNOSI** (solriamfetol) prior authorization may be approved if member meets the following criteria: ● Member is 18 years of age or older AND ● Member has diagnosis of either narcolepsy or obstructive sleep apnea (OSA) and is experiencing excessive daytime sleepiness AND ● Member does not have end stage renal disease AND ● If Sunosi is being prescribed for OSA, member has 1 month trial of CPAP AND ● Member has trial and failure‡ of modafinil AND armodafinil AND one other agent in stimulant PDL class. **WAKIX** (solriamfetol) prior authorization may be approved if member meets the following criteria: ● Member is 18 years of age or older **AND** ● Member has diagnosis of narcolepsy and is experiencing excessive daytime sleepiness **AND** ● Member does not have end stage renal disease (eGFR <15 mL/minute) **AND** ● Member does not have severe hepatic impairment **AND** ● Member does not have a history QT interval prolongation **AND** ● Member has trial and failure‡ of modafinil **AND** armodafinil **AND** one other agent in stimulant PDL class **AND** ● Member has been counseled that Wakix may reduce the efficacy of hormonal contraceptives and regarding use an alternative non-hormonal method of contraception during Wakix therapy and for at least 21 days after discontinuing treatment. Maximum Dose (all products): See Table 2 **Exceeding Max Dose:** Prior authorization may be approved for doses that are higher than the listed maximum dose (Table 2) for members meeting the following criteria: • Member is taking medication for indicated use listed in Table 1 **AND** • Member has 30 day trial and failure‡ of three different preferred or non-preferred agents at maximum doses listed in Table 2 **AND** • Documentation of member's symptom response to maximum doses of three other agents is provided **AND** • Member is not taking a sedative hypnotic medication (such as temazepam, triazolam, or zolpidem from the Sedative Hypnotic PDL class).

	QUILLIVANT XR (methylphenidate) suspension RELEXXII (methylphenidate ER) RITALIN (methylphenidate) STRATTERA (atomoxetine) SUNOSI (solriamfetol) WAKIX (pitolisant) ZENZEDI (dextroamphetamine)	‡Failure is defined as: lack of efficacy with 4 week trial, allergy, intolerable side effects, or significant drug-drug interaction.

Table 1: Indications and Age

- Approval for medically accepted indications not listed in Table 1 may be given with prior authorization review and may require submission of peer-reviewed literature or medical compendia showing safety and efficacy of the medication used for the prescribed indication.
- Preferred medications may also receive approval for off-label use for fatigue associated with multiple sclerosis if meeting all other criteria for approval.
- **Bolded drug names are preferred** (subject to preferential coverage changes for brand/generic equivalents)

Drug	Indication/Age
Stimulants–Immediate Release	
Amphetamine sulfate (EVEKEO)	ADHD (Age ≥ 3 years), Narcolepsy (Age ≥ 6 years)
Dexmethylphenidate IR (FOCALIN)	ADHD (Age ≥ 6 years)
Dextroamphetamine IR (ZENZEDI)	ADHD (Age 3 to≤ 16 years), Narcolepsy (Age ≥ 6 years)
Dextroamphetamine solution (PROCENTRA)	ADHD (Age 3 to ≤ 16 years), Narcolepsy (Age ≥ 6 years)
Methamphetamine (DESOXYN)	ADHD (Age ≥ 6 years)
methylphenidate IR (METHYLIN, RITALIN)	ADHD (Age ≥ 6 years†), Narcolepsy (Age ≥ 6 years), OSA. †Prior Authorization for members 4-6 years of age with a diagnosis of ADHD may be approved with prescriber attestation to the following: • Member's symptoms have not significantly improved despite adequate behavior interventions AND • Member experiences moderate-to-severe continued disturbance in functioning AND • Prescriber has determined that the potential benefits of starting methylphenidate before the age of 6 years outweigh the potential harm of delaying treatment.
Methylphenidate XR ODT (CONTEMPLA XR ODT)	ADHD (Age ≥ 6 years)
Mixed amphetamine salts IR (ADDERALL)	ADHD (Age ≥ 3 years), Narcolepsy (Age ≥ 6 years)
Stimulants –Extended-Release	
Amphetamine ER (ADZENYS XR-ODT and ADZENYS ER suspension)	ADHD (Age ≥ 6 years)
Amphetamine ER (DYANAVEL XR)	ADHD (Age ≥ 6 years)

Mixed-amphetamine salts ER (**ADDERALL XR**)	ADHD (Age ≥ 6 years)
Dexmethylphenidate ER **(Focalin XR)**	ADHD (Age ≥ 6 years)
Dextroamphetamine ER (DEXEDRINE)	ADHD (Age 3 to ≤ 16 years), Narcolepsy (Age ≥ 6 years)
Dextroamphetamine ER/amphetamine ER (MYDAYIS ER)	ADHD (Age ≥ 13 years)
Lisdexamfetamine dimesylate (**VYVANSE capsule, VYVANSE chewable**)	ADHD (Age ≥ 6 years), Moderate to severe binge eating disorder in adults (Age ≥ 18 years)
Methylphenidate ER OROS **(CONCERTA)**	ADHD (Age ≥ 6 years), Narcolepsy (Age ≥ 6 years), OSA
Methylphenidate SR (METADATE ER)	ADHD (Age ≥ 6 years), Narcolepsy (Age ≥ 6 years)
Methylphenidate ER (METADATE CD)	ADHD (Age ≥ 6 years)
Methylphenidate ER (QUILLICHEW ER)	ADHD (Age ≥ 6 years), Narcolepsy (Age ≥ 6 years)
Methylphenidate ER (QUILLIVANT XR)	ADHD (Age ≥ 6 years), Narcolepsy (Age ≥ 6 years)
Methylphenidate ER (RITALIN LA)	ADHD (Age ≥ 6 years)
Methylphenidate ER (APTENSIO XR)	ADHD (Age ≥ 6 years)
Methylphenidate XR ODT (CONTEMPLA XR ODT)	ADHD (Age ≥ 6 years)
Methylphenidate ER (JORNAY PM)	ADHD (Age ≥ 6 years)
Non-Stimulants	
Atomoxetine (STRATTERA)	ADHD (Age ≥ 6 years)
Clonidine ER (KAPVAY)	ADHD (Age ≥ 6 years), Treatment of ADHD as adjunct to stimulants
Guanfacine ER (INTUNIV)	ADHD (Age ≥ 6 years), Treatment of ADHD as adjunct to stimulant
Wakefulness-promoting Agents	
Armodafinil (NUVIGIL)	Excessive sleepiness associated with narcolepsy, OSA, and SWD (Age ≥ 18 years)
Modafinil (PROVIGIL)	Excessive sleepiness associated with narcolepsy, OSA, SWD, and adjunct therapy to treat fatigue and sleepiness in patients with major depressive disorder (MDD) (Age ≥ 18 years)
Pitolisant (WAKIX)	Excessive sleepiness associated with narcolepsy (Age ≥ 18 years)
Solriamfetol (SUNOSI)	Excessive sleepiness associated with narcolepsy, OSA (Age ≥ 18 years)
KEY: **ADHD**–attention-deficit/hyperactivity disorder, **OSA**–obstructive sleep apnea, **SWD**–shift work disorder	

Table 2: Maximum Dose

Drug	Maximum Daily Dose
ADDERALL	60 mg/day
ADDERALL XR	60mg/day
ADZENYS XR-ODT® | ADZENYS ER-SUSPENSION	18.8 mg/day (age 6-12) | 12.5 mg/day (age >13)
AMPHETAMINE SALTS	40 mg/day
CONCERTA	54 mg/day or 72 mg/day >age 13
COTEMPLA XR-ODT	51.8mg/day
DESOXYN	25mg/day

DEXEDRINE	40mg/day
DEXTROSTAT	40mg/day
DYANAVEL XR	20mg/day
FOCALIN	20 mg/day
FOCALIN XR	40 mg/day
JORNAY PM	100mg/day
METHYLPHNIDATE ER	60 mg/day
MYDAYIS ER	25 mg/day (age 13-17) | 50 mg/day (age ≥ 18)
INTUNIV ER	4 mg/day
RITALIN IR	60 mg/day
RITALIN SR	60 mg/day
RITALIN LA	60 mg/day
STRATTERA	100 mg/day
VYVANSE CAPS AND CHEWABLE	70 mg/day
D-AMPHETAMINE ER	40 mg/day
DAYTRANA	30 mg/day
EVEKEO	40 mg/day
KAPVAY ER	0.4 mg/day
METHYLIN ER	60 mg/day
METHYLIN	60 mg/day
METHYLIN SUSPENSION	60 mg/day
METADATE CD	60mg/day
METADATE ER	60mg/day
METHYLPHENIDATE	60 mg/day
PROVIGIL	400 mg/day
NUVIGIL	250 mg/day
QUILLIVANT	60 mg/day
SUNOSI	150 mg/day
WAKIX	35.6mg/day
ZENZEDI ®	40 mg/day

Therapeutic Drug Class: **TRIPTANS AND OTHER MIGRAINE TREATMENTS - Oral -***Effective 1/1/2021*

No PA Required (quantity limits may apply)	**PA Required**
Eletriptan tablet (generic Relpax)	Almotriptan tablet
Naratriptan tablet (generic Amerge)	AMERGE (naratriptan) tablet
Rizatriptan tablet, ODT (generic Maxalt)	FROVA (frovatriptan) tablet
	Frovatriptan tablet

Non-preferred oral triptan products may be approved for members who have trialed and failed three preferred oral products. Failure is defined as lack of efficacy with 4 week trial, allergy, intolerable side effects or significant drug-drug interaction.

Quantity Limits:

Amerge (naratriptan), Frova (frovatriptan), Imitrex (sumatriptan), Zomig (zolmitriptan)	Max 9 tabs/30 days
Treximet (sumatriptan/naproxen)	Max 9 tabs/30 days
Axert (almotriptan) and Relpax (eletriptan)	Max 6 tabs/30 days

Sumatriptan tablet (generic Imitrex)	IMITREX (sumatriptan) tablet MAXALT (rizatriptan) tablet, MLT RELPAX (eletriptan) tablet REYVOW (lasmiditan) tablet Sumatriptan/Naproxen tablet TREXIMET (sumatriptan/naproxen) tablet Zolmitriptan tablet, ODT ZOMIG (zolmitriptan) tablet, ZMT	<table><tr><td>Maxalt (rizatriptan)</td><td>Max 12 tabs/30 days</td></tr><tr><td>Reyvow (lasmiditan)</td><td>Max 8 tabs/30 days</td></tr></table>

Therapeutic Drug Class: **TRIPTANS AND OTHER MIGRAINE TREATMENTS - Non-Oral -***Effective 1/1/2020*

No PA Required (quantity limits may apply)	**PA Required**	
IMITREX[BNR] (sumatriptan) nasal spray Sumatriptan vial	IMITREX (sumatriptan) cartridge, injection, kit, pen injector, syringe ONZETRA XSAIL (sumatriptan) nasal powder Sumatriptan cartridge, kit, nasal spray, pen injector, syringe, vial TOSYMRA (sumatriptan) nasal spray ZEMBRACE SYMTOUCH (sumatriptan) injection ZOMIG (zolmitriptan) nasal spray	**Zembrace Symtouch injection**, **Tosymra nasal spray**, or **Onzetra Xsail nasal powder** may be approved for members who have trialed and failed one preferred non-oral triptan products AND two oral triptan agents with different active ingredients. Failure is defined as lack of efficacy with 4 week trial, allergy, intolerable side effects, significant drug-drug interaction, or documented inability to take alternative dosage form. All other non-preferred products may be approved for members who have trailed and failed one preferred non-oral triptan product AND one preferred oral triptan product. Failure is defined as lack of efficacy with 4 week trial, allergy, intolerable side effects or significant drug-drug interactions, documented inability to tolerate dosage form. **Quantity Limits:** <table><tr><td>Imitrex (sumatriptan) injection</td><td>Max 4 injectors / 30 days</td></tr><tr><td>Imitrex (sumatriptan) nasal spray</td><td>Max 6 inhalers / 30 days</td></tr><tr><td>Onzetra Xsail (sumatriptan) nasal powder</td><td>Max 16 nosepieces / 30 days</td></tr><tr><td>Tosymra (sumatriptan) nasal spray</td><td>Max 12 nasal spray devices / 30 days</td></tr><tr><td>Zembrace Symtouch (sumatriptan) injection</td><td>Max 36mg / 30 days</td></tr><tr><td>Zomig (zolmitriptan) nasal spray</td><td>Max 6 inhalers / 30 days</td></tr></table> **Grandfathering:** Members currently stabilized on ZOMIG (zolmitriptan) nasal spray may receive approval to continue therapy with that product at the prescribed dose, not exceeding 6 inhalers per 30 days.

V. Dermatological

Therapeutic Drug Class: **ACNE – Topical -***Effective 7/1/2020*

No PA Required (if age and diagnosis criteria is met*)	PA Required	
*Adapalene gel *Adapalene/benzoyl peroxide (generic Epiduo) *Clindamycin phosphate solution, medicated swab *Clindamycin/benzoyl peroxide gel jar (generic Benzaclin) *Clindamycin/benzoyl peroxide (generic Duac) *DIFFERIN (adapalene) gel pump BNR *Erythromycin solution *Sulfacetamide sodium suspension *Tretinoin cream, gel	ACANYA (clindamycin/benzoyl peroxide) gel, pump ACZONE (dapsone) gel, pump Adapalene cream, gel pump, solution AKLIEF (trifarotene) cream ALTRENO (tretinoin) lotion AMZEEQ (minocycline) foam ATRALIN (tretinoin) gel AVAR (sulfacetamide sodium) (all products) AVITA (tretinoin) AZELEX (azelaic acid) cream BENZACLIN (clindamycin/benzoyl peroxide) (all products) BENZAMYCIN (erythromycin) gel BP (sulfacetamide sodium) wash CLEOCIN (clindamycin) gel, lotion, pledgets Clindamycin phosphate gel, lotion, foam Clindamycin/benzoyl peroxide pump Clindamycin/tretinoin Dapsone gel, pump DIFFERIN (adapalene) cream, gel, lotion DUAC (clindamycin/benzoyl peroxide)	Authorization for all acne agents prescribed solely for cosmetic purposes will not be approved. Preferred topical acne agents prescribed for members > 25 years of age will require prior authorization and will be approved following prescriber verification that the medication is not being utilized for cosmetic purposes AND prescriber verification that the indicated use is for acne vulgaris, psoriasis, cystic acne, disorders of keratinization, neoplasms, or comedonal acne. These medications are only eligible for prior authorization approval for the aforementioned diagnoses. Preferred topical acne agents prescribed for members ≤ 25 years of age may be approved for members with a diagnosis of acne vulgaris, psoriasis, cystic acne, disorders of keratinization, neoplasms, or comedonal acne. Diagnosis will be verified through automated verification (AutoPA) of the appropriate corresponding ICD-10 diagnosis code related to the indicated use of the medication. In addition to the above criteria, preferred topical clindamycin and erythromycin products may also be approved for a diagnosis of folliculitis, hidradenitis suppurativa, or perioral dermatitis (erythromycin only). Approval of preferred topical clindamycin and erythromycin products for other medically accepted indications may be considered following clinical prior authorization review by a call center pharmacist. Non-preferred topical products may be approved for members meeting all of the following criteria: ● Member has trialed/failed three preferred topical products with different mechanisms (i.e. tretinoin, antibiotic). Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction AND ● Prescriber verification that the medication is being prescribed for one of the following diagnoses: acne vulgaris, psoriasis, cystic acne, disorders of keratinization, neoplasms, or comedonal acne.

	EPIDUO (adapalene/benzoyl peroxide) (all products) Erythromycin gel, med swab Erythromycin / Benzoyl peroxide EVOCLIN (clindamycin) foam FABIOR (tazarotene) foam KLARON (sulfacetamide) lotion NEUAC (clindamycin/benzoyl peroxide) gel ONEXTON (clindamycin/benzoyl peroxide) OVACE (sulfacetamide sodium) (all products) RETIN-A (tretinoin) (all products) RETIN-A MICRO (tretinoin) (all products) ROSULA (sulfacetamide sodium/ sulfur) cloths, wash Sulfacetamide sodium cleanser Sulfacetamide sodium/ sulfur cleanser, cream, cleanser kit, lotion, wash Tazarotene cream TAZORAC (tazarotene) cream, gel Tretinoin gel (generic Atralin) Tretinoin microspheres (all products) ZIANA (clindamycin/tretinoin) gel	

Therapeutic Drug Class: **ACNE – ISOTRETINOIN** -*Effective 7/1/2020*		
PA Required for all agents		
AMNESTEEM capsule CLARAVIS capsule	ABSORICA capsule ABSORICA LD capsule Isotretinoin capsule MYORISAN capsule ZENATANE capsule	Preferred products may be approved for severe, recalcitrant nodulocystic acne for adults and children ≥ 12 years of age that have been unresponsive to conventional therapy. Non-preferred products may be approved for members meeting the following: ● Member has trialed/failed two preferred agents (failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction) AND ● Member is an adult or child ≥ 12 years of age with severe, recalcitrant nodulocystic acne and has been unresponsive to conventional therapy.
Therapeutic Drug Class: **ANTI-PSORIATICS - Oral** -*Effective 1/1/2021*		
No PA Required	**PA Required**	
Acitretin capsule	Methoxsalen capsule OXSORALEN-ULTRA (methoxsalen) capsule SORIATANE (acitretin) capsule	Prior authorization for non-preferred oral agents will be approved with failure of two preferred anti-psoriatic agents, one of which must be a preferred oral agent. Failure is defined as lack of efficacy of a 4-week trial, allergy, intolerable side effects or significant drug-drug interaction.
Therapeutic Drug Class: **ANTI-PSORIATICS -Topical** -*Effective 1/1/2021*		
No PA Required	**PA Required**	
Calcipotriene solution DOVONEX [BNR] (calcipotriene) cream TACLONEX SCALP [BNR] (calcipotriene/betamethasone) suspension TACLONEX OINTMENT [BNR] (calcipotriene/betamethasone)	Calcipotriene cream, ointment Calcipotriene/betamethasone dp ointment Calcitriol ointment DUOBRII (halobetasol/tazarotene) lotion ENSTILAR (calcipotriene/betamethasone) foam SORILUX (calcipotriene) foam VECTICAL (calcitriol) ointment	Prior authorization for non-preferred topical agents will be approved with failure of two preferred topical agents. If non-preferred topical agent being requesting is a combination product, trial of two preferred agents must include a preferred combination agent. Failure is defined as lack of efficacy of a 4-week trial, allergy, intolerable side effects or significant drug-drug interaction. Preferred and non-preferred products that contain a corticosteroid ingredient (such as betamethasone) will be limited to 4 weeks of therapy. Continued use will require one week of steroid-free time in between treatment periods. Members with >30% of their body surface area affected may not use Enstilar (calcipotriene/betamethasone DP) foam or Taclonex (calcipotriene/betamethasone DP) ointment products as safety and efficacy have not been established.
Therapeutic Drug Class: **TOPICAL IMMUNOMODULATORS** – *Effective 7/1/2020*		
No PA Required	**PA Required**	Non-preferred topical immunomodulator products may be approved following adequate trial and failure‡ of one prescription topical corticosteroid AND two preferred agents. ‡Failure is defined as a lack of efficacy with one month trial, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions.
Pimecrolimus cream - *authorized generic only -Oceanside Pharm* PROTOPIC (tacrolimus)[BNR]	ELIDEL (pimecrolimus) Pimecrolimus cream - *All other manufacturers*	

	Tacrolimus (generic Protopic)	For members under 18 years of age, must be prescribed by or in conjunction with a dermatologist or allergist/immunologist.
Therapeutic Drug Class: **ROSACEA AGENTS** -*Effective 7/1/2020*		
No PA Required Azelaic acid gel Metronidazole cream, gel, lotion	**PA Required** FINACEA (azelaic acid) foam, gel METROCREAM (metronidazole) METROGEL (metronidazole) METROLOTION (metronidazole) MIRVASO (brimonidine) ORACEA (doxycycline)* tablet NORITATE (metronidazole) RHOFADE (oxymetazoline) ROSADAN Kit (metronidazole) SOOLANTRA (ivermectin)	Prior authorization for non-preferred products in this class may be approved if member meets the following criteria: ● Member has a diagnosis of persistent (non-transient) facial erythema with inflammatory papules and pustules due to rosacea AND ● Prescriber attests that medication is not being used solely for cosmetic purposes AND ● Member has tried and failed two preferred agents of different mechanisms of action (Failure is defined as lack of efficacy with 4 week trial, allergy, intolerable side effects) *Oracea® (doxycycline monohydrate DR) may be approved if the member meets all of the following criteria: ● Member has taken generic doxycycline for a minimum of three months and failed therapy in the last 6 months. Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions AND ● Member has history of an adequate trial/failure (8 weeks) of 2 other preferred agents (oral or topical). Failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions AND ● Member is ≥ 18 years of age and has been diagnosed with rosacea with inflammatory lesions
Therapeutic Drug Class: **TOPICAL STEROIDS** – *Effective 4/1/2020*		
Low potency		
No PA Required *Brand/generic changes effective 01/01/21* Hydrocortisone (Rx) cream, ointment, lotion DERMA-SMOOTHE-FS BNR (fluocinolone acetonide) oil Desonide 0.05% cream, ointment Fluocinolone acetonide 0.01% cream	**PA Required** ALA-CORT (hydrocortisone) cream ALA-SCALP (hydrocortisone) lotion Alclometasone cream, ointment CAPEX (fluocinolone) shampoo DESONATE (desonide) gel Desonide lotion DESOWEN (desonide) cream	Non-preferred Low Potency topical corticosteroids may be approved following adequate trial and failure of two preferred agents in the Low Potency class (failure is defined as lack of efficacy with 4 week trial, allergy, intolerable side effects or significant drug-drug interactions).

	Fluocinolone acetonide 0.01% body oil, 0.01% scalp oil, 0.01% solution MICORT-HC (hydrocortisone) cream SYNALAR (fluocinolone) 0.01% solution TEXACORT (hydrocortisone) solution	
Medium potency		
No PA Required Betamethasone dipropionate 0.05% lotion Betamethasone valerate 0.1% ointment Fluticasone propionate 0.05% cream, 0.05% ointment Mometasone furoate 0.1% cream, 0.1% ointment, 0.1% solution Triamcinolone acetonide 0.025% cream, 0.1% cream, 0.025% ointment, 0.1% ointment, 0.025% lotion, 0.1% lotion	**PA Required** BESER (fluticasone) lotion Betamethasone dipropionate 0.05% cream Betamethasone valerate 0.1% cream, 0.1% lotion, 0.12% foam Clocortolone cream, cream pump CLODERM (clocortolone) cream, cream pump CORDRAN (flurandrenolide) tape CUTIVATE (fluticasone) cream, lotion DERMATOP (prednicarbate) ointment DERMATOP EMOLLIENT (prednicarbate) cream Diflorasone cream ELOCON (mometasone) cream Fluocinolone acetonide 0.025% cream, ointment Fluocinonide-E cream 0.05% Flurandrenolide cream, ointment, lotion	Non-preferred Medium Potency topical corticosteroids may be approved following adequate trial and failure of two preferred agents in the Medium Potency class (failure is defined as: lack of efficacy with 4 week trial, allergy, intolerable side effects or significant drug-drug interactions).

	Fluticasone propionate 0.05% lotion Hydrocortisone butyrate 0.1% cream, 0.1% lotion, 0.1% solution, 0.1% ointment, 0.1% lipid/lipocream Hydrocortisone valerate 0.2% cream, 0.2% ointment KENALOG (triamcinolone) spray LOCOID (hydrocortisone butyrate) cream, ointment, lotion, solution LOCOID LIPOCREAM 0.1% (hydrocortisone butyrate) LUXIQ (betamethasone valerate) foam ORALONE (triamcinolone) paste PANDEL (hydrocortisone probutate) cream Prednicarbate cream, ointment PSORCON (diflorasone) cream SERNIVO (betamethasone dipropionate) spray SYNALAR (fluocinolone) 0.025% cream/kit, ointment/kit SYNALAR TS (fluocinolone) 0.01% Triamcinolone 0.1% paste, 0.147 mg/gm spray	
High potency		
No PA Required (unless exceeds duration of therapy*) *Betamethasone dipropionate propylene glycol (aug) 0.05% cream	**PA Required** Amcinonide cream, lotion APEXICON-E (diflorasone) cream	Non-preferred High Potency topical corticosteroids may be approved following adequate trial and failure of two preferred agents in the High Potency class (failure is defined as lack of efficacy with 4 week trial, allergy, intolerable side effects or significant drug-drug interactions).

*Fluocinonide 0.05% gel, 0.05% solution, 0.05% ointment *Triamcinolone acetonide 0.5% cream, 0.5% ointment	Betamethasone dipropionate 0.05% ointment Desoximetasone cream, gel, ointment Diflorasone ointment Fluocinonide 0.05% cream Halcinonide cream HALOG (halcinonide) cream, ointment TOPICORT (desoximetasone) cream, gel, ointment TRIANEX (triamcinolone) Ointment	*All High Potency topical corticosteroids will require prior authorization beyond 4 weeks of therapy. The provider will be encouraged to transition to a moderate or low potency topical steroid after this time has elapsed.
Very high potency		
No PA Required (unless exceeds duration of therapy*) *Betamethasone dipropionate propylene glycol (aug) 0.05% ointment *Clobetasol 0.05% cream, 0.05% gel, 0.05% ointment, 0.05% solution	**PA Required** Betamethasone dipropionate propylene glycol (aug) 0.05% gel, 0.05% lotion BRYHALI (halobetasol) lotion Clobetasol emollient/emulsion cream, foam Clobetasol lotion, foam, spray, shampoo CLOBEX (clobetasol) 0.05% lotion, 0.05% spray, 0.05% shampoo CLODAN (clobetasol) 0.05% shampoo, kit Desoximetasone spray DIPROLENE (betamethasone dipropionate/glycol) ointment Fluocinonide 0.1% cream Halobetasol cream, ointment, foam	Non-preferred Very High Potency topical corticosteroids may be approved following adequate trial and failure of clobetasol propionate in the same formulation as the product being requested (if the formulation of the requested non-preferred product is not available in preferred clobetasol product options, then trial and failure of any preferred clobetasol product formulation will be required). Failure is defined as lack of efficacy with 2-week trial, allergy, intolerable side effects or significant drug-drug interactions. *All Very High Potency topical corticosteroids will require prior authorization beyond 2 weeks of therapy. If clobetasol propionate shampoo is being used to treat plaque psoriasis, then prior authorization will be required beyond 4 weeks of therapy. The provider will be encouraged to transition to a moderate or low potency topical steroid after this time has elapsed.

	IMPEKLO (clobetasol) lotion LEXETTE (halobetasol) foam OLUX (clobetasol) foam OLUX-E (clobetasol) foam TEMOVATE (clobetasol) cream, ointment TOPICORT (desoximetasone) spray TOVET EMOLLIENT (clobetasol) foam ULTRAVATE (halobetasol) lotion, cream, ointment ULTRAVATE-X (halobetasol/lactic acid) cream, ointment VANOS (fluocinonide) cream	

VI. Endocrine

Therapeutic Drug Class: **ANDROGENIC AGENTS** -*Effective 7/1/2020*

PA Required for all agents in this class		
*ANDRODERM (testosterone) patch * Testosterone gel 1.62% pump (generic Androgel) *Testosterone gel packet (generic Vogelxo) *Testosterone cypionate IM injection ***Injectable testosterone cypionate is a pharmacy benefit when self-administered. Administration in an office setting is a medical benefit.***	ANDROGEL 1.62% (testosterone gel) pump ANDROGEL 1% (testosterone gel) ANDROID (methyltestosterone) capsule DEPO-TESTOSTERONE (testosterone cypionate) IM injection FORTESTA (testosterone) gel JATENZO (testosterone undecanoate) capsules METHITEST (methyltestosterone) tablet	<u>Hypogonadotropic or Primary Hypogonadism (may be secondary to Klinefelter Syndrome):</u> Preferred products may be approved for members meeting the following: 1. Member is a male patient <u>≥</u> 16 years of age with a documented diagnosis of hypogonadotropic or primary hypogonadism OR ≥ 12 years of age with a diagnosis of hypogonadotropic or primary hypogonadism secondary to Klinefelter Syndrome (all other diagnoses will require manual review) AND 2. Member has two documented low serum testosterone levels below the lower limit of normal range for testing laboratory prior to initiation of therapy AND 3. Member does not have a diagnosis of breast or prostate cancer AND 4. Member does not have a palpable prostate nodule or prostate-specific antigen (PSA) > 4ng/mL (not required for members < 40 years of age) AND 5. Has baseline hematocrit < 50% Reauthorization Criteria (requests for renewal of a currently expiring prior authorization for a preferred product may be approved for members meeting the following criteria):

	Methyltestosterone capsule STRIANT (testosterone) buccal TESTIM (testosterone) gel TESTRED (methyltestosterone) capsule Testosterone 1.62% packet (generic Androgel) Testosterone gel (generic Fortesta, Testim, Vogelxo) Testosterone gel pump (generic Axiron, Vogelxo) Testosterone enanthate IM injection VOGELXO (testosterone) gel XYOSTED (testosterone enanthate) SC injection	• Member is a male patient ≥ 16 years of age with a documented diagnosis of hypogonadotropic or primary hypogonadism OR ≥ 12 years of age with a diagnosis of hypogonadotropic or primary hypogonadism secondary to Klinefelter Syndrome AND • Serum testosterone is being regularly monitored (at least annually) to achieve total testosterone level in the middle tertile of normal reference range AND • Member does not have a diagnosis of breast or prostate cancer AND • Has hematocrit < 54% Gender Transition/Affirming Hormone Therapy: Preferred androgenic drugs will be approved for members meeting the following: 1. Female sex assigned at birth > 16 years of age AND 2. Is undergoing female to male transition AND 3. Has a negative pregnancy test prior to initiation AND 4. Has baseline hematocrit < 50% or hematocrit < 54% for continuation of therapy. Non-Preferred Products: Non-preferred **topical** androgenic agents may be approved for patients meeting the above criteria with trial and failed‡ therapy with two preferred topical androgen formulations. Non-preferred **injectable** androgenic agents may be approved for patients meeting the above criteria with trial and failed‡ therapy with a preferred injectable androgenic drug. Prior authorization for **oral** androgen agents (tablet, capsule, buccal) may be approved if member has trialed and failed‡ therapy with a preferred topical agent AND testosterone cypionate injection. ‡Failure is defined as lack of efficacy with 8 week trial, allergy, intolerable side effects, contraindication to, or significant drug-drug interaction. For all agents and diagnoses, members < 16 years of age will require a manual prior authorization review by a pharmacist (with exception of members ≥ 12 years of age with a diagnosis of hypogonadotropic or primary hypogonadism secondary to Klinefelter Syndrome).
Therapeutic Drug Class: **BONE RESORPTION SUPPRESSION AND RELATED AGENTS -***Effective 10/1/2020*		
Bisphosphonates		
No PA Required Alendronate (generic) 5mg, 10mg, 35mg, 70mg tablets Ibandronate tablet	**PA Required** ACTONEL (risedronate) ACTONEL w/Calcium (risedronate w/calcium) Alendronate 40mg tab Alendronate oral solution	Non-preferred bisphosphonates may be approved for members who have failed treatment with one preferred product at treatment dose. Failure is defined as lack of efficacy with a 12-month trial, allergy, intolerable side effects, or significant drug-drug interaction. **ALENDRONATE 70mg/75ml solution** may also be approved without trial of a preferred agent for members that cannot swallow solid oral dosage forms or members that have a feeding tube.

	ATELVIA (risedronate) BINOSTO (alendronate) BONIVA (ibandronate) DIDRONEL (etidronate) FOSAMAX (alendronate) FOSAMAX plus D (alendronate w/D) Etidronate Risedronate	**ETIDRONATE** may also be approved without trial of a preferred agent for members with a diagnosis of heterotopic ossification. For members who have a low risk of fracture, discontinuation of bisphosphonate therapy and drug holiday should be considered following 5 years of treatment. Low risk is defined as having a bone mineral density, based on the most recent T-score, of greater than (better than) -2.5 AND no history of low trauma or fragility fracture.
Non-Bisphosphonates		
	PA Required Calcitonin salmon (nasal) EVISTA (raloxifene) FORTEO (teriparatide) Raloxifene (oral) Teriparatide (subcutaneous) TYMLOS (abaloparatide)	**CALCITONIN SALMON (nasal)** may be approved if the member meets the following criteria: ● Member has a diagnosis of post-menopausal osteoporosis (BMD T-scores of -2.5 or less) **AND** ● Has trial and failure of preferred bisphosphonate for 12 months (failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction) **OR** ● Member cannot swallow solid oral dosage forms or has a feeding tube. Quantity limit: One spray daily **RALOXIFENE** may be approved if the member meets the following criteria: ● Diagnosis of postmenopausal osteoporosis (BMD T-scores of -2.5 or less) **AND** ● Has trial and failure of preferred bisphosphonate for one year (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction) Maximum dose: 60mg daily **FORTEO** (teriparatide) may be approved if the member meets the following criteria: ● Member has one of the following diagnoses: o Osteoporosis, (BMD T-scores of -2.5 or less) primary or hypogonadal in men o Osteoporosis due to corticosteroid use o Postmenopausal osteoporosis **AND** ● Member has trial and failure of preferred bisphosphonate for one year (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction) **AND** ● Prior authorization will be given for one year and total exposure of parathyroid hormone analogs (Forteo and Tymlos) shall not exceed two years Maximum dose: 20mcg daily **TYMLOS** (abaloparatide) may be approved if the member meets the following criteria: ● Member has a diagnosis of postmenopausal

		osteoporosis (BMD T-scores of -2.5 or less) **AND** ● Has trial and failure of preferred bisphosphonate for one year (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction) **AND** ● Prior authorization will be given for one year and total exposure of parathyroid hormone analogs (Forteo and Tymlos) shall not exceed two years. Maximum dose: 80 mcg daily All other non-preferred non-bisphosphonates may be approved for members who have failed treatment with one preferred bisphosphonate product at treatment dose. Failure is defined as lack of efficacy with a 12-month trial, allergy, intolerable side effects, or significant drug-drug interaction. *Note: Prior authorization criteria for Prolia (denosumab) is listed on Appendix P.*

Therapeutic Drug Class: **CONTRACEPTIVES - Oral** *Effective 10/1/2020*

No PA Required		**PA Required**	
Monophasic 28: Altavera 28 0.15-30 Apri 28 0.15-30 Aubra 28 0.1-20 Aubra EQ-28 0.1-20 Aviane 28 0.1-20 Balziva 28 0.4-35 **No PA Required** Cryselle 28 0.3-30 Cyclafem 28 1-35 Dasetta 28 1-35 Drospirenone-Eth Estradiol-Levomefolate 28 3-20 Drospirenone-Eth Estradiol-Levomefolate 28 3-30 Elinest 28 0.3-30 Enskyce 28 0.15-30 Estarylla 28 0.25-35 Ethynodiol-Eth Estra 28 1-50 Falmina 28 0.1-20 Femynor 28 0.25-35 Isibloom 28 0.15-30 Juleber 28 0.15-30 Kelnor 28 1-35 Kurvelo 28 0.15-30 Larissia 28 0.1-20 Lessina 28 0.1-20 Levonor-Eth Estrad 28 0.1-20 Levonor-Eth Estrad 28 0.15-30	**Monophasic 28:** Levora 28 0.15-30 Lillow 28 0.15-30 Low-Ogestrel 28 0.3-30 Lutera 28 0.1-20 Marlissa 28 0.15-30 Mili 28 0.25-35 **No PA Required** Mono-Linyah 28 0.25-35 Necon 28 0.5-35 Norg-Ethin Estra 28 0.25-35 Nortrel 28 0.5-35 Nortrel 28 1-35 Ocella 28 3-30 Orsythia 28 1-20 Philith 28 0.4-35 Pirmella 28 1-35 Portia 28 0.15-30 Previfem 28 0.25-35 Sprintec 28 0.25-35 Sronyx 28 0.1-20 Syeda 28 3-30 Vienva 28 0.1-20 Vyfemla 28 0.4-35 Wera 28 0.5-35 Zarah 28 3-30	All other rebateable products are non-preferred	Non-preferred oral contraceptive products will be approved if member fails one-month trial with four preferred agents OR if preferred products with medically necessary ingredients and/or doses are unavailable. (Failure is defined as: allergy, intolerable side effects, or significant drug-drug interaction) Initial fills may be dispensed for three-month supply to establish tolerance (i.e. lack of adverse effects). After established tolerance on the same agent for 3 months, a 12-month supply (365 days) may be dispensed (as one fill).

No PA Required **Biphasic:** Azurette 28 Bekyree 28 Cyred 28 Desogest-Eth Estra 28 Emoquette 28 Kariva 28 Lo Loestrin FE 28 1-10 Mircette 28 Viorele 28 **Triphasic:** Alyacen 7-7-7 28 Caziant 7-7-7 28 Cyclafem 7-7-7 28 Dasetta 7-7-7 28 Enpresse 28 Levonest 28 Levonor-Eth Estrad Triphasic 28 Norgestimate-Eth Estrad 0.18-0.215-0.25/0.025 Norgestimate-Eth Estrad 0.18-0.215-0.25/0.035 Pirmella 7-7-7 Tri-Estarylla 28 Tri Femynor 28 Tri-Linyah 28 Tri-Lo-Estarylla 28 Tri-Lo-Marzia 28 Tri-Lo-Sprintec 28 Tri-Previfem 28 Tri-Sprintec 28 Tri-Vylibra Lo 28 Velivet 7-7-7 28 **Norethindrone Only:** Camila 28 0.35 Deblitane 28 0.35 Errin 28 0.35 Heather 28 0.35 Jencycla 28 0.35 Jolivette 28 0.35 Norethindrone 28 0.35 Norlyda 28 0.35 Sharobel 28 0.35	**No PA Required** **Monophasic 21:** Larin 21 1-20 Larin 21 1.5-30 Norethind-Eth Estrad 21 1-20 Nortrel 21 1-35 **Extended Cycle:** Amethia 91 0.03 – 0.15 – 0.01 Ashlyna 91 0.15-10-30 Introvale 91 0.15-30 Jolessa 91 0.15-30 Levonorgest-Eth Estrad 0.09-20 Levonorgest-Eth Estrad 91 0.1-10-20 Levonorgest-Eth Estrad 91 0.15-0.03 Levonorgest-Eth Estrad 91 0.15-0.03-0.01 Levonorgest-Eth Estrad 91 0.15-20-25-30 Setlakin 91 0.15-30 **Continuous Cycle:** Aurovela FE 1-20 Aurovela FE 1.5-30 Blisovi FE 1-20 Blisovi FE 1.5-30 Jasmiel 3-20 Junel FE 1-20 Junel FE 1.5-30 Junel FE 24 1-20 Larin FE 1-20 Larin FE 24 1-20 Larin FE 1.5-30 Loryna 3-20 Microgestin FE 1-20 Nikki 3-20 Noreth-Eth Estrad-FE 24 1-20 Noreth-Eth Estrad-FE 1-20 Tarina FE 24 1-20 Tarina FE 1-20 Tarina FE 1-20 EQ		

Therapeutic Drug Class: **DIABETES MANAGEMENT CLASSES, INSULINS**- *Effective 4/1/2020*		
Rapid-Acting		
No PA Required	**PA Required**	Non-preferred products may be approved following trial and failure of treatment with two preferred products (failure is defined as allergy [hives, maculopapular rash, erythema multiforme, pustular rash, severe hypotension, bronchospasm, and angioedema] or intolerable side effects). **Afrezza** (human insulin) may be approved if meeting the following criteria: • Member is 18 years or older AND • Member has trialed and failed treatment with two preferred products (failure is defined as allergy [hives, maculopapular rash, erythema multiforme, pustular rash, severe hypotension, bronchospasm, and angioedema] or intolerable side effects) AND • Member must not have chronic lung disease such as COPD or asthma AND • If member is a type 1 diabetic, must use in conjunction with long-acting insulin AND • Member must not be a smoker
NOVOLOG (insulin aspart) cartridge, vial, FlexTouch HUMALOG (insulin lispro) cartridge, vial, KwikPen, pen HUMALOG Jr. (insulin lispro) KwikPen	ADMELOG (insulin lispro) vial, Solostar AFREZZA (regular insulin) cartridge, unit APIDRA (insulin glulisine) vial, Solostar FIASP (insulin aspart) vial, FlexTourch, PenFill Insulin lispro pen, vial	
Short-Acting		
No PA Required	**PA Required**	Non-preferred products may be approved following trial and failure of treatment with one preferred product (failure is defined as allergy or intolerable side effects).
HUMULIN R (insulin regular) vial (OTC) HUMULIN R (insulin regular) concentrated vial, Kwikpen (U-500)	NOVOLIN R (insulin regular) vial (OTC) HUMULIN R (insulin regular) KwikPen (OTC)	
Intermediate-Acting		
No PA Required	**PA Required**	Non-preferred products may be approved following trial and failure of treatment with one preferred product (failure is defined as allergy or intolerable side effects).
HUMULIN N (insulin NPH) vial, Kwikpen (OTC)	NOVOLIN N (insulin NPH) vial (OTC)	
Long-Acting		
No PA Required	**PA Required**	Non-preferred products may be approved if the member has failed treatment with Levemir AND Lantus (failure is defined as allergy or intolerable side effects).
LEVEMIR (insulin detemir) vial, FlexTouch LANTUS (insulin glargine) vial, Solostar	BASAGLAR (insulin glargine) KwikPen TOUJEO (insulin glargine) Solostar TOUJEO MAX (insulin glargine) Solostar TRESIBA (insulin degludec) vial, FlexTouch	

Mixtures		
No PA Required HUMULIN 70/30 vial, Kwikpen (OTC) HUMALOG MIX 50/50 vial, Kwikpen HUMALOG MIX 75/25 vial, Kwikpen NOVOLOG MIX 70/30 vial, FlexPen	**PA Required** NOVOLIN 70/30 vial, FlexPen (OTC)	Non-preferred products may be approved if the member has failed treatment with two of the preferred products (failure is defined as: allergy or intolerable side effects).
Therapeutic Drug Class: **DIABETES MANAGEMENT CLASSES, NON- INSULINS**- *10/1/2020*		
Amylin		
	PA Required SYMLIN (pramlintide)	**SYMLIN** (pramlintide) may be approved following trial and failure of metformin AND trial and failure of a DPP4-inhibitor or GLP-1 analogue. Failure is defined as lack of efficacy (such as not meeting hemoglobin A1C goal despite adherence to regimen) following three month trial, allergy, intolerable side effects, or a significant drug-drug interaction. Prior authorization may be approved for Symlin (pramlintide) products for members with a diagnosis of diabetes mellitus Type 1 without requiring trial and failure of other products. Maximum Dose: Prior authorization will be required for doses exceeding FDA-approved dosing listed in product package labeling.
Biguanides		
No PA Required Metformin 500mg, 850mg, 1000mg tablets Metformin ER 500mg tablets (generic Glucophage XR)	**PA Required** FORTAMET (metformin) GLUCOPHAGE (metformin) GLUCOPHAGE XR (metformin XR) GLUMETZA ER (metformin) Metformin ER 750mg Metformin ER (generic Fortamet, Glumetza) RIOMET (metformin) solution RIOMET ER (metformin) suspension	Non-preferred products may be approved for members who have failed treatment with two preferred products. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. Liquid metformin may be approved for members who meet one of the following: • Member is under the age of 12 with a feeding tube **OR** Prescriber confirms that member has difficulty swallowing

Dipeptidyl Peptidase-4 Enzyme inhibitors (DPP-4is)

*Must meet eligibility criteria	PA Required	
*JANUVIA (sitagliptin) *TRADJENTA (linagliptin)	Alogliptin NESINA (alogliptin) ONGLYZA (saxagliptin)	*Approval for preferred products require a 3-month trial of (or documented contraindication to) metformin therapy prior to initiation of therapy. Non-preferred DPP-4 inhibitors may be approved after a member has failed a 3-month trial of metformin AND a 3-month trial of two preferred products. Failure is defined as lack of efficacy (such as not meeting hemoglobin A1C goal despite adherence to regimen), allergy, intolerable side effects, or a significant drug-drug interaction. <u>Maximum Dose:</u> Prior authorization will be required for doses exceeding the FDA-approved maximum dosing listed in the following table:

DPP4	FDA-Approved Max Dose (mg/day)
Alogliptin (generic Nesina)	25 mg/day
Januvia (sitagliptin)	100 mg/day
Nesina (alogliptin)	25 mg/day
Onglyza (saxagliptin)	5 mg/day
Tradjenta (linagliptin)	5 mg/day

DPP-4 Inhibitors – Combination with Metformin

*Must meet eligibility criteria	PA Required	
*JANUMET (sitagliptin/metformin) *JANUMET XR (sitagliptin/metformin)	Alogliptin/metformin JENTADUETO (linagliptin/metformin) JENTADUETO XR (linagliptin/metformin) KAZANO (alogliptin/metformin) KOMBIGLYZE (saxagliptin/metformin)	*Approval for preferred combination agent products require a 3-month trial of (or documented contraindication to) metformin therapy prior to initiation of therapy. Non-preferred combination products may be approved for members who have been stable on the two individual ingredients of the requested combination for three months AND have had adequate three-month trial and failure of a preferred combination agent. Failure is defined as lack of efficacy (such as not meeting hemoglobin A1C goal despite adherence to regimen), allergy, intolerable side effects, or a significant drug-drug interaction.

Glucagon-like Peptide-1 Receptor Agonists (GLP-1 Analogues)

*Must meet eligibility criteria	PA Required	
*BYETTA (exenatide) *BYDUREON (exenatide ER)	ADLYXIN (lixisenatide) BYDUREON BCISE (exenatide ER)	*Approval for preferred products requires a 3-month trial of (or documented contraindication to) metformin therapy prior to initiation of therapy. Non-preferred products may be approved following trial and failure of a 3-month trial of metformin AND a 3-month trial of two preferred products. Failure is defined as lack of

<table>
<tr>
<td>*VICTOZA (liraglutide)</td>
<td>OZEMPIC (semaglutide)

RYBELSUS (semaglutide)

TRULICITY (dulaglutide)</td>
<td>efficacy (such as not meeting hemoglobin A1C goal despite adherence to regimen), allergy, intolerable side effects, limited dexterity resulting in the inability to administer doses of a preferred product, or a significant drug-drug interaction.

<u>Maximum Dose:</u>
Prior authorization is required for all products exceeding maximum dose listed in product package labeling.

<table>
<tr><th colspan="2">Maximum Dose</th></tr>
<tr><td>Adlyxin (lixisenatide)</td><td>20mcg per day</td></tr>
<tr><td>Bydureon (exenatide)</td><td>2mg weekly</td></tr>
<tr><td>Bydureon BCISE (exenatide)</td><td>2mg weekly</td></tr>
<tr><td>Byetta (exenatide)</td><td>20mcg per day</td></tr>
<tr><td>Ozempic (semaglutide)</td><td>1mg weekly</td></tr>
<tr><td>Trulicity (dulaglutide)</td><td>1.5mg weekly</td></tr>
<tr><td>Victoza (liraglutide)</td><td>1.8mg per day</td></tr>
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<tr><td colspan="3">Other Hypoglycemic Combinations</td></tr>
<tr>
<td></td>
<td>PA Required

Alogliptin/pioglitazone

AVANDARYL (rosiglitazone/glimepiride)

DUETACT (pioglitazone/glimepiride)

Glipizide/metformin

GLUCOVANCE (glyburide/metformin)

Glyburide/metformin

GLYXAMBI (empagliflozin/linagliptin)

METAGLIP (glipizide/metformin)

OSENI (alogliptin/pioglitazone)

Pioglitazone/glimepiride

QTERN (dapagliflozin/saxagliptin)

SOLIQUA (insulin glargine/lixisenatide)

STEGLUJAN (ertugliflozin/sitagliptin)</td>
<td>Non-preferred products may be approved for members who have been stable on each of the individual ingredients in the requested combination for 3 months (including cases where the ingredients are taken as two separate 3-month trials or when taken in combination for at least 3 months).</td>
</tr>
</table>

	TRIJARDY XR (empagliflozin/linagliptin/metformin) XULTOPHY (insulin degludec/liraglutide)	
Meglitinides		
	PA Required Nateglinide PRANDIN (repaglinide) Repaglinide STARLIX (nateglinide)	Non-preferred products may be approved for members who have failed treatment with one sulfonylurea. Failure is defined as: lack of efficacy (such as not meeting hemoglobin A1C goal despite adherence to regimen), allergy, intolerable side effects, or significant drug-drug interaction.
Meglitinides Combination with Metformin		
	PA Required Repaglinide/metformin	Non-preferred products may be approved for members who have been stable on the two individual ingredients of the requested combination for 3 months.
Sodium-Glucose Cotransporter 2 inhibitors (SGLT-2is)		
No PA Required FARXIGA (dapagliflozin) INVOKANA (canagliflozin) JARDIANCE (empagliflozin)	**PA Required** STEGLATRO (ertugliflozin)	Non-preferred products may receive approval following trial and failure with two preferred products. Failure is defined as lack of efficacy with 3-month trial (such as not meeting hemoglobin A1C goal despite adherence to regimen), allergy, intolerable side effects, or a significant drug-drug interaction. <u>Maximum Dose:</u> Prior authorization is required for all products exceeding maximum dose listed in product package labeling.
SGLT-2 Inhibitors Combination with Metformin		
No PA Required INVOKAMET (canagliflozin/metformin) XIGDUO XR (dapagliflozin/metformin)	**PA Required** INVOKAMET XR (canagliflozin/metformin) SEGLUROMET (ertugliflozin/metformin) SYNJARDY (empagliflozin/metformin)	Non-preferred products may be approved for members who have been stable on the two individual ingredients of the requested combination for 3 months.

	SYNJARDY XR (empagliflozin/metformin)	
Thiazolidinediones (TZDs)		
No PA Required Pioglitazone	**PA Required** ACTOS (pioglitazone) AVANDIA (rosiglitazone)	Non-preferred agents may be approved following trail and failure of metformin AND trial and failure of one preferred product. Failure is defined as lack of efficacy (such as not meeting hemoglobin A1C goal despite adherence to regimen) with a 3-month trial, allergy, intolerable side effects, or a significant drug-drug interaction.
Thiazolidinediones Combination with Metformin		
	PA Required ACTOPLUS MET (pioglitazone/metformin) ACTOPLUS MET XR (pioglitazone/metformin) Pioglitazone/metformin	Non-preferred products may be approved for members who have been stable on the two individual ingredients of the requested combination for 3 months.
Therapeutic Drug Class: **GLUCAGON, SELF-ADMINISTERED** -*Effective 4/1/2020*		
No PA Required **(*Must meet eligibility criteria)** GLUCAGEN HYPOKIT (glucagon) Glucagon Emergency Kit GVOKE (glucagon)*	**PA Required** BAQSIMI (glucagon) Nasal Spray	***Gvoke (glucagon)** may be approved following trial and failure of GlucaGen (glucagon) OR glucagon emergency kit (failure is defined as allergy to ingredients in product, intolerable side effects, or inability to administer dosage form). Non-preferred products may be approved if the member has failed treatment with Gvoke (glucagon) AND one other preferred product (failure is defined as allergy to ingredients in product, intolerable side effects, or contraindication to dosing form). Quantity limit: 2 doses per year unless used / damaged / lost
Therapeutic Drug Class: **GROWTH HORMONES** -*Effective 4/1/2020*		
No PA Required **(if diagnosis and dose met)** GENOTROPIN NORDITROPIN	**PA Required** HUMATROPE NUTROPIN AQ OMNITROPE SAIZEN SEROSTIM	All preferred products may be approved if the member has one of the qualifying diagnoses listed below (diagnosis may be verified through AutoPA) AND if prescription does not exceed limitations for maximum dosing (Table 1). Non-preferred Growth Hormones may be approved if the following criteria are met: • Member failed treatment with one preferred growth hormone product (failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions). • Member has a qualifying diagnosis: o Prader-Willi o Chronic renal insufficiency/failure requiring transplantation (defined as Creatinine Clearance < 30mL/min) o Turner's Syndrome

	ZOMACTON ZORBTIVE	○ Hypopituitarism: as a result of pituitary disease, hypothalamic disease, surgery, radiation therapy or trauma verified by one of the following: ▪ Has failed at least one GH stimulation test (peak GH level < 10 ng/mL) ▪ Has at least one documented low IGF-1 level (below normal range for patient's age – refer to range on submitted lab document) ▪ Has deficiencies in ≥ 3 pituitary axes (i.e. TSH, LH, FSH, ACTH, ADH) ○ Cachexia associated with AIDS ○ Noonan Syndrome ○ Short bowel syndrome ○ Neonatal symptomatic growth hormone deficiency (limited to three month PA approval) • Prescription does not exceed limitations for maximum dosing (Table 1) based on prescriber submission/verification of patient weight from most recent clinical documentation

Table 1: Growth Hormone Product Maximum Dosing*

Medication	Pediatric Max Dosing (age < 18 years)	Adult Max Dosing (age ≥ 18 years)
Genotropin	0.33 mg/kg/week	0.08 mg/kg/week
Humatrope	0.375 mg/kg/week	0.0875 mg/kg/week
Norditropin Flexpro	0.47 mg/kg/week	0.112 mg/kg/week
Nutropin AQ Nuspin	0.357 mg/kg/week	0.175 mg/kg/week for ≤35 years of age 0.0875 mg/kg/week for >35 years of age
Omnitrope	0.33 mg/kg/week	0.08 mg/kg/week
Saizen	0.18 mg/kg/week	0.07 mg/kg/week
Serostim	Not Indicated	42 mg/week for cachexia with HIV only (in combination with antiretroviral therapy)
Zomacton	0.375 mg/kg/week	0.0875 mg/kg/week
Zorbtive	Not Indicated	8 mg/28 days for short bowel syndrome only
*Based on FDA labeled indications and dosing		

VII. Gastrointestinal

Therapeutic Drug Class: **BILE SALTS** -*Effective 4/1/2020*

No PA Required	PA Required	
Ursodiol capsule Ursodiol tablet	ACTIGALL (ursodiol) capsule CHENODAL (chenodiol) tablet CHOLBAM (cholic acid) capsule OCALIVA (obeticholic acid) tablet	**Chenodal** (chenodiol) and **Actigall** (ursodiol) may be approved for members who meet the following criteria: • Member ≥ 18 years of age AND • Member has tried and failed therapy with a 12-month trial of a preferred ursodiol (failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions). **Cholbam** (cholic acid) may be approved for members who meet the following criteria: • Bile acid synthesis disorders:

	URSO (ursodiol) tablet URSO FORTE (ursodiol) tablet	○ Member must be greater than 3 weeks old in age AND ○ Member has a diagnosis for bile acid synthesis disorder due to single enzyme defect (Single Enzyme-Defect Disorders: Defective sterol nucleus synthesis, 3β-hydroxy-Δ-c27-steroid oxidoreductase deficiency, AKR1D1 deficiency, CYP7A1 deficiency, Defective side-chain synthesis, CYP27A1 deficiency (cerebrotendinous xanthomatosis), 2-methylacyl-CoA racemase deficiency (AMACR), 25-hydroxylation pathway (Smith–Lemli-Opitz). • Peroxisomal disorder including Zellweger spectrum disorders: ○ Member must be greater than 3 weeks old in age AND ○ Member has diagnosis of peroxisomal disorders (PDs) including Zellweger spectrum disorders AND ○ Member has manifestations of liver disease, steatorrhea or complications from decreased fat-soluble vitamin absorption. **Ocaliva** (obeticholic acid), **Urso** (ursodiol), and **Urso Forte** (ursodiol) may be approved for members meeting the following criteria: • Member is ≥ 18 years of age AND • Medication is prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant provider AND • Member has the diagnosis of Primary Biliary Cholangitis as evidenced by two of the following at the time of diagnosis: ○ Evidence of cholestasis with an alkaline phosphatase elevation of at least 1.5 times the upper limit of normal ○ Presence of antimitochondrial antibody: a titer of 1:40 or higher ○ Histologic evidence of nonsuppurative destruction cholangitis and destruction of interlobular bile ducts AND • Member has failed treatment with a preferred ursodiol product for at least 1 year with an inadequate response OR • Member has intolerable side effects, drug-drug interaction, or allergy to preferred ursodiol formulation.
Therapeutic Drug Class: **ANTI-EMETICS, Oral -***Effective 1/1/2021*		
No PA Required Doxylamine/pyridoxine tablet (generic Diclegis) (*Analog Pharma only)* Meclizine (Rx) tablet Metoclopramide solution, tablet Ondansetron ODT, tablet Ondansetron oral suspension/ solution* (<5 years)	**PA Required** AKYNZEO (netupitant/palonosetron) capsule Aprepitant capsule, tripack BONJESTA ER (doxylamine/pyridoxine) tablet DICLEGIS DR (doxylamine/pyridoxine) tablet Doxylamine 25mg (OTC) tablet	**Ondansetron solution** may be approved for members < 5 years and those members ≥ 5 years of age with a feeding tube. **Emend (aprepitant) TriPack** or **Emend (aprepitant) powder kit** may be approved following trial and failure of two preferred products AND Emend (aprepitant) capsule. Failure is defined as lack of efficacy with 14-day trial, allergy, intolerable side effects, or significant drug-drug interaction. D**iclegis DR tablet (brand) BONJESTA (doxylamine/pyridoxine)** may be approved for 9 months if meeting the following criteria: ● Member has nausea and vomiting associated with pregnancy **AND** ● Member has trialed and failed generic doxylamine/pyridoxine DR tablet (generic Diclegis) AND one of the following (failure is defined as lack of efficacy with a 7-day trial, allergy, intolerable side effects, or significant drug-drug interaction):

Prochlorperazine tablet Promethazine syrup, tablet Trimethobenzamide capsule	Dronabinol capsule EMEND (aprepitant) capsule, powder for suspension, dose/tri pack Granisetron tablet MARINOL (dronabinol) capsule Metoclopramide ODT Pyridoxine 50mg or 100mg (OTC) tablet REGLAN (metoclopramide) tablet TIGAN (trimethobenzamide) capsule VARUBI (rolapitant) tablet ZOFRAN (ondansetron) tablet ZUPLENZ (ondansetron) film	○ Antihistamine (such as diphenhydramine, dimenhydrinate, meclizine) **OR** ○ Dopamine antagonist (such as metoclopramide, prochlorperazine, promethazine) **OR** ○ Serotonin antagonist (ondansetron, granisetron) All other non-preferred products may be approved for members who have trialed and failed treatment with two preferred products. Failure is defined as lack of efficacy with 14-day trial, allergy, intolerable side effects, or significant drug-drug interaction. **Dronabinol** prior authorization may be approved for members meeting above non-preferred criteria OR via AutoPA for members with documented HIV diagnosis.
Therapeutic Drug Class: **ANTI-EMETICS, Non-Oral** -*Effective 1/1/2021*		
No PA Required *Brand/generic changes effective 02/18/21* PHENADOZ (promethazine) 12.5mg, 25 mg suppository Prochlorperazine suppository Promethazine 12.5 mg, 25 mg suppository Scopolamine patch	**PA Required** COMPRO (prochlorperazine) suppository Promethazine 50 MG suppository PROMETHEGAN (Promethazine) 50 mg suppository SANCUSO (granisetron) patch TRANSDERM-SCOP (scopolamine) patch	All other non-preferred products may be approved for members who have trialed and failed treatment with two preferred products. Failure is defined as lack of efficacy with 14-day trial, allergy, intolerable side effects, or significant drug-drug interaction.
Therapeutic Drug Class: **GI MOTILITY, CHRONIC** -*Effective 10/1/2020*		
PA Required for all agents in this class		All agents will only be approved for FDA labeled indications and up to FDA approved maximum doses (listed below): Preferred agents may be approved if the member meets the following criteria:
AMITIZA (lubiprostone)	Alosetron	

LINZESS (linaclotide) MOVANTIK (naloxegol)	LOTRONEX (alosetron) MOTEGRITY (prucalopride) RELISTOR (methylnaltrexone) tablet, syringe SYMPROIC (naldemedine) TRULANCE (plecanatide) VIBERZI (eluxadoline)	● Has diagnosis of Irritable Bowel Syndrome – Constipation (IBS-C), Chronic Idiopathic Constipation (CIC), or Opioid Induced Constipation (OIC) in patients with opioids prescribed for noncancer pain **AND** ● Member does not have a diagnosis of GI obstruction **AND** ● For indication of OIC, member opioid use must exceed 4 weeks of treatment ● For indications of CIC, OIC, IBS-C; member must have documentation of adequate trial of two or more over-the-counter motility agents (for example; polyethylene glycol, docusate, bisocodyl) (Failure is defined as a lack of efficacy for a 7 day trial, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions) o If the member cannot take oral medications, then the member must fail a 7-day trial with a nonphosphate enema (docusate or bisocodyl enema) ● For indication of IBS-D; must have documentation of adequate trial with loperamide **AND** dicyclomine **OR** hyoscamine (Failure is defined as a lack of efficacy for a 7 day trial, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions). Non-preferred agents may be approved if the member meets the following criteria: ● Member meets all listed criteria for preferred agents **AND** ● Member has trialed and failed two preferred agents o If indication OIC caused by methadone, then non-preferred agent may be approved after trial of Movantik (Failure is defined as a lack of efficacy for a 7 day trial, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions) **AND** o Member meets additional criteria for the agents listed below **VIBERZI** (eluxadoline) may be approved for members who meet the following criteria: ● Has diagnosis of Irritable Bowel Syndrome – Diarrhea (IBS-D) AND ● Member has a gallbladder AND ● Member does not have severe hepatic impairment (Child-Pugh C), history of severe constipation, known mechanical gastrointestinal obstruction, biliary duct obstruction, history of pancreatitis or structural disease of the pancreas AND ● Member does not drink more than 3 alcoholic drinks per day AND **LOTRONEX** (alesotron) and generic alesotron may be approved for members who meet the following criteria: ● Member is a female with Irritable Bowel Syndrome – Diarrhea (IBS-D) with symptoms lasting 6 months or longer AND ● Member does not have severe hepatic impairment (Child-Pugh C), history of severe constipation or ischemic colitis, hypercoagulable state, Crohn's disease or ulcerative colitis, or known mechanical gastrointestinal obstruction

Medication	FDA approved indication	FDA Max Dose
Amitiza (lubiprostone)	IBS-C (females only), CIC, OIC (not caused by methadone)	48mcg/day
Linzess (linaclotide)	IBS-C, CIC	290mcg/day
Movantik (naloxegol)	OIC	25mg/day
Viberzi (eluxadoline)	IBS-D	200mg/day
Relistor syringe (methylnaltrexone)	OIC	12mg SQ/day
Relistor oral (methylnaltrexone)	OIC	450mg/day
Lotronex (alosetron)	IBS-D (females only)	2mg/day (females only)
Symproic (Naldemedine)	OIC	0.2mg/day
Trulance (plecanatide)	CIC, IBS-C	3mg/day
Motegrity (prucalopride)	CIC	2mg/day

CIC – chronic idiopathic constipation, OIC – opioid induced constipation, IBS – irritable bowel syndrome, D – diarrhea predominant, C – constipation predominant

Therapeutic Drug Class: **H. PYLORI TREATMENTS** -*Effective 1/1/2021*

No PA Required	PA Required	
PYLERA (bismuth subcitrate/ metronidazole/ tetracycline) tablet	Amoxicillin/ lansoprazole/ clarithromycin HELIDAC (bismuth subsalicylate/ metronidazole/ tetracycline OMECLAMOX-PAK (amoxicillin/ omeprazole/clarithromycin) TALICIA (omeprazole/amoxicillin/ rifabutin)	Non-preferred *H. pylori* treatments should be used as individual product ingredients unless one of the individual products is not commercially available, then a PA for the combination product may be given.

Therapeutic Drug Class: **HEMORRHOIDAL AND RELATED ANORECTAL AGENTS** - *Effective 4/1/2020*

No PA Required	PA Required	
CORTIFOAM (hydrocortisone) aerosol Hydrocortisone enema Hydrocortisone 2.5% cream with applicator Hydrocortisone-Pramoxine 1%-1% cream	ANA-LEX (hydrocortisone-lidocaine) ANUSOL-HC (hydrocortisone) cream COLOCORT (hydrocortisone) enema CORTENEMA (hydrocortisone) enema Hydrocortisone 1% cream with applicator	Non-preferred products may be approved following trial and failure of therapy with 3 preferred products (failure is defined as lack of efficacy with 4 week trial, allergy, intolerable side effects or significant drug-drug interactions). **Rectiv** (nitroglycerin) ointment may be approved if meeting the following: • Member has a diagnosis of anal fissure AND • Prescriber attests that member has trialed and maximized use of appropriate supportive therapies including sitz bath, fiber, topical analgesics (such as lidocaine), and stool softeners/laxatives.

Lidocaine-Hydrocortisone 3-0.5% cream PROCTOFOAM (hydrocortisone-pramoxine) PROCTO-MED HC (hydrocortisone) 2.5% cream PROCTO-PAK (hydrocortisone) 1% cream PROCTOSOL-HC 2.5% (hydrocortisone) cream PROCTOZONE-HC 2.5% (hydrocortisone) cream	Lidocaine-Hydrocortisone 3-0.5% cream kit Lidocaine-Hydrocortisone 3-2.5% gel MICORT-HC (hydrocortisone) cream RECTIV (nitroglycerin) ointment	
Therapeutic Drug Class: **PANCREATIC ENZYMES** -*Effective 1/1/2021*		
No PA Required CREON (pancrelipase) capsule ZENPEP (pancrelipase) capsule	**PA Required** PANCREAZE (pancrelipase) capsule PERTZYE (pancrelipase) capsule VIOKACE (pancrelipase) tablet	Non-preferred products will be approved for members who have failed an adequate trial (4 weeks) with at least two preferred products. (Failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interaction.) Grandfathering: Members currently stabilized on a Non-preferred pancreatic enzyme can receive approval to continue on that agent for one year if medically necessary.
Therapeutic Drug Class: **PROTON PUMP INHIBITORS** -*Effective 1/1/2021*		
No PA Required Esomeprazole DR capsule RX Lansoprazole DR capsules RX NEXIUM (esomeprazole) packets BNR Omeprazole DR capsule RX Pantoprazole tablet PREVACID Solutab BNR (lansoprazole) (members < 2)	**PA Required** ACIPHEX (rabeprazole) tablet, sprinkle capsule DEXILANT (dexlansoprazole) capsule Esomeprazole DR 49.3 capsule RX, packets Esomeprazole DR capsule OTC Lansoprazole DR capsule OTC, ODT RX NEXIUM (esomeprazole) capsule RX, 24HR OTC	For members treating GERD symptoms that are controlled on PPI therapy, it is recommended that the dose of the PPI be re-evaluated or step-down with an H2 blocker (such as famotidine or ranitidine) be trialed in order to reduce long-term PPI use. Prior authorization for non-preferred proton pump inhibitors may be approved if all of the following criteria are met: ● Member has a qualifying diagnosis (below) **AND** ● Member has trailed and failed therapy with three preferred agents within the last 24 months. (Failure is defined as: lack of efficacy following 4 week trial, allergy, intolerable side effects, or significant drug-drug interaction) **AND** ● Member has been diagnosed using one of the following diagnostic methods: o Diagnosis made by GI specialist o Endoscopy o X-ray o Biopsy o Blood test

	Omeprazole/Na bicarbonate capsule, packet Omeprazole DR 20mg tablet, ODT (OTC) PREVACID (lansoprazole) capsule, suspension PRILOSEC (omeprazole) suspension PROTONIX (pantoprazole DR) tablet, suspension Rabeprazole tablet ZEGERID (omeprazole/Na bicarbonate) capsule, packet	○ Breath Test **Qualifying Diagnoses:** Barrett's esophagus, duodenal ulcer, erosive esophagitis, gastric ulcer, GERD, GI Bleed, H. pylori infection, hypersecretory conditions (Zollinger-Ellison), NSAID-induced ulcer, pediatric esophagitis, requiring mechanical ventilation, requiring a feeding tube **Quantity Limits:** All agents will be limited to once daily dosing except when used for the following diagnoses: Barrett's esophagus, GI Bleed, H. pylori, hypersecretory conditions (Zollinger-Ellison), or Spinal Cord Injury patients with associated acid reflux. **Adult members with GERD** on once daily, high-dose PPI therapy who continue to experience symptoms may receive initial prior authorization approval for a 4-week trial of twice daily, high-dose PPI therapy. Continuation of the twice daily dosing regimen for GERD beyond 4 weeks will require additional prior authorization approval verifying adequate member response to the dosing regimen and approval may be placed for one year. If a member with symptomatic GERD does not respond to twice daily, high-dose PPI therapy, this should be considered a treatment failure. **Pediatric members (< 18 years of age)** on once daily dosing of a PPI who continue to experience symptoms may receive one-year prior authorization approval for twice daily PPI therapy. **Age Limits:** **Nexium 24H** and **Zegerid** will not be approved for members less than 18 years of age. **Prevacid Solutab** will be approved for members < 2 years of age OR for members ≥ 2 years of age with a feeding tube.
Therapeutic Drug Class: **NON-BIOLOGIC ULCERATIVE COLITIS AGENTS- Oral -***Effective 1/1/2021*		
No PA Required APRISO ER [BNR] (mesalamine ER) capsule LIALDA (mesalamine DR) [BNR] tablet PENTASA (mesalamine) capsule Sulfasalazine IR and DR tablet	**PA Required** ASACOL HD (mesalamine DR) tablet AZULFIDINE (sulfasalazine) Entab, tablet Balsalazide capsule Budesonide DR tablet COLAZAL (balsalazide) capsule DELZICOL (mesalamine DR) capsule	Prior authorization for non-preferred oral formulations will require trial and failure of two preferred oral products with different active ingredients AND a preferred rectal product. If inflammation is not within reach of topical therapy, trial of preferred rectal product is not required. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. **Uceris (budesonide) tablet**: If the above criteria is met, Uceris (budesonide) tablet prior authorization will be approved for 8 weeks. Further prior authorization may be approved if 7 days of steroid-free time has elapsed and member continues to meet the above criteria.

	DIPENTUM (olsalazine) capsule Mesalamine DR (generic Asacol HD, Lialda) tablet Mesalamine capsule (generic Apriso ER) UCERIS (budesonide) tablet	
Therapeutic Drug Class: **NON-BIOLOGIC ULCERATIVE COLITIS AGENTS- Rectal -***Effective 1/1/2021*		
No PA Required Mesalamine suppository Mesalamine 4gm/60 ml enema (generic SF ROWASA)	**PA Required** CANASA (mesalamine) suppository Mesalamine enema, kit ROWASA (mesalamine w/cleansing wipes) SF Rowasa (mesalamine enema) UCERIS (budesonide) foam	Prior authorization for non-preferred rectal formulations will require trial and failure of one preferred rectal formulation and one preferred oral formulation (Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction). **Uceris (budesonide) foam**: If the above criteria is met, Uceris (budesonide) foam prior authorization will be approved for 6 weeks. Further prior authorization may be approved if 7 days of steroid-free time has elapsed and member continues to meet the above criteria.

VIII. Hematological

Therapeutic Drug Class: **ANTICOAGULANTS- Oral -***Effective 10/1/2020*		
No PA Required Warfarin tablet PRADAXA (dabigatran) capsule XARELTO (rivaroxaban) 10 mg, 15 mg, 20 mg tablet, dose pack	**PA Required** BEVYXXA (betrixaban) tablet ELIQUIS (apixaban) tablet SAVAYSA (edoxaban) TABLET XARELTO (rivaroxaban) 2.5 mg tablet	**BEVYXXA** (betrixaban) may be approved if all the following criteria have been met: ● The member has trialed and failed therapy with two preferred agents. (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction) **AND** ● Member is not on dialysis **AND** ● The member is need of prophylaxis for DVT following hospitalization for an acute medical illness who are at risk for thromboembolic events due to limited mobility **AND** ● The member does not have a mechanical prosthetic heart valve **ELIQUIS** (apixaban) may be approved if the following criteria have been met: ● The member is on dialysis or has chronic renal failure **OR** ● The member has failed therapy with one preferred agent. Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. If the member is on dialysis or has chronic renal failure, trial and failure of preferred agents is not required **AND** ● The member does not have a mechanical prosthetic heart valve **AND** ● Eliquis (apixaban) is being prescribed for one of the following indications: o Deep vein thrombosis (DVT) **OR**

		○ In need of DVT prophylaxis following knee or hip replacement surgery **OR** ○ Pulmonary embolism (PE) **OR** ○ Non-valvular atrial fibrillation **OR** ○ Venous thromboembolism (VTE) in the setting of malignancy **SAVAYSA** (edoxaban) may be approved if all the following criteria have been met: ● The member has failed therapy with two preferred agents. (Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction) **AND** ● Member is not on dialysis **AND** ● Member does not have CrCl > 95 mL/min **AND** ● The member has a diagnosis of deep vein thrombosis (DVT), pulmonary embolism (PE) **OR** ● The member has a diagnosis of non-valvular atrial fibrillation **AND** ● The member does not have a mechanical prosthetic heart valve **XARELTO 2.5mg** (rivaroxaban) may be approved for members meeting all of the following criteria: ● Xarelto 2.5mg is being prescribed to reduce major CV events in members diagnosis of chronic coronary artery disease (CAD) or peripheral artery disease **AND** ● Xarelto 2.5mg is being taken twice daily and in combination with aspirin 75-100mg daily **AND** ● Member must not be receiving dual antiplatelet therapy, other non-aspirin antiplatelet therapy, or other oral anticoagulant **AND** ● Member must not have had an ischemic, non-lacunar stroke within the past month **AND** ● Member must not have had a hemorrhagic or lacunar stroke at any time All other non-preferred oral agents require trial and failure of two preferred oral agents. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. Continuation of Care: Members with current prior authorization approval on file for a non-preferred <u>oral</u> anticoagulant medication may continue to receive approval for that medication
Therapeutic Drug Class: **ANTICOAGULANTS- Parenteral** -*Effective 10/1/2020*		
No PA Required *Brand/generic changes effective 02/18/21* Enoxaparin syringe Enoxaparin vial	**PA Required** ARIXTRA (fondaparinux) syringe Fondaparinux (generic Arixtra) FRAGMIN (dalteparin) vial, syringe LOVENOX (enoxaparin) syringe, vial	Non-preferred parenteral anticoagulants may be approved if member has trial and failure of one preferred parenteral agent. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction **ARIXTRA** (fondaparinux) may be approved if the following criteria have been met: ● Member is 18 years of age or older **AND** ● Member has a CrCl > 30 ml/min **AND** ● Member weighs > 50 kg **AND** ● Member has a documented history of heparin induced-thrombocytopenia **OR**

<table>
<tr><td></td><td></td><td>

- Member has a contraindication to enoxaparin

Grandfathering: Members currently stabilized on fondaparinux (Arixtra) and dalteparin (Fragmin) may receive prior authorization approval to continue on that medication.
</td></tr>
<tr><td colspan="3">Therapeutic Drug Class: ANTI-PLATELETS -Effective 1/1/2021</td></tr>
<tr><td>No PA Required

AGGRENOX (ASA/dipyridamole) capsule

ASA/dipyridamole ER capsule

BRILINTA (tigacrelor) tablet

Cilostazol tablet

Clopidogrel tablet

Dipyridamole tablet

Pentoxifylline ER tablet

Prasugrel tablet</td><td>PA Required

EFFIENT (prasugrel) tablet

PLAVIX (clopidogrel) tablet

ZONTIVITY (vorapaxar) tablet</td><td>Patients taking Brilinta (ticagrelor) must also be taking a maintenance dose of aspirin not exceeding 100 mg/day.

Zontivity (vorapaxar) will be approved for patients with a diagnosis of myocardial infarction or peripheral artery disease without a history of stroke, transient ischemic attack, intracranial bleeding, or active pathological bleeding. Patients must also be taking aspirin and/or clopidogrel concomitantly.

Non-preferred products without criteria will be reviewed on a case by case basis.</td></tr>
<tr><td colspan="3">Therapeutic Drug Class: COLONY STIMULATING FACTORS -Effective 10/1/2020</td></tr>
<tr><td colspan="2">PA Required for all agents in this class*</td><td rowspan="2">*Prior authorization for preferred agents may be approved if meeting the following criteria:
• Medication is being used for one of the following indications:
o Cancer patient receiving myelosuppressive chemotherapy –to reduce incidence of infection (febrile neutropenia) (Either the post nadir ANC is less than 10,000 cells/mm3 or the risk of neutropenia for the member is calculated to be greater than 20%)
o Acute Myeloid Leukemia (AML) patients receiving chemotherapy
o Bone Marrow Transplant (BMT)
o Peripheral Blood Progenitor Cell Collection and Therapy
o Hematopoietic Syndrome of Acute Radiation Syndrome
o Severe Chronic Neutropenia (Evidence of neutropenia infection exists or ANC is below 750 cells/mm3)
AND
• For Udenyca (pegfilgrastim-cbqv), the member meets the following criteria:
o Member has trial and failure of Neupogen. Failure is defined as lack of efficacy, intolerable side effects, drug-drug interaction, or contraindication to Neupogen therapy. Trial and failure of Neupogen will not be required if meeting one of the following:</td></tr>
<tr><td>NEUPOGEN (filgrastim) vial, syringe

UDENYCA (pegfilgrastim-cbqv)</td><td>FULPHILA (pegfilgrastim-jmdb)

GRANIX (tbo-filgrastim)

LEUKINE (sargramostim)

NEULASTA (pegfilgrastim) syringe

NIVESYM (filgrastim-aafi)

ZARXIO (filgrastim-sndz)

ZIEXTENZO (pegfilgrastim-bmez)</td></tr>
</table>

<table>
<tr><td></td><td></td><td>

Member has limited access to caregiver or support system for assistance with medication administration OR
Member has inadequate access to healthcare facility or home care interventions.

Prior authorization for non-preferred agents may be approved if meeting the following criteria:

Medication is being used for one of the following indications:

Cancer patient receiving myelosuppressive chemotherapy –to reduce incidence of infection (febrile neutropenia) (Either the post nadir ANC is less than 10,000 cells/mm3 or the risk of neutropenia for the member is calculated to be greater than 20%)
Acute Myeloid Leukemia (AML) patients receiving chemotherapy
Bone Marrow Transplant (BMT)
Peripheral Blood Progenitor Cell Collection and Therapy
Hematopoietic Syndrome of Acute Radiation Syndrome
Severe Chronic Neutropenia (Evidence of neutropenia infection exists or ANC is below 750 cells/mm3)

AND
Member has history of trial and failure of Neupogen AND Udenyca. Failure is defined as a lack of efficacy with a 3-month trial, allergy, intolerable side effects, significant drug-drug interactions, or contraindication to therapy. Trial and failure of Neupogen will not be required if meeting one of the following:

Member has limited access to caregiver or support system for assistance with medication administration OR
Member has inadequate access to healthcare facility or home care interventions.

</td></tr>
<tr><td colspan="3">Therapeutic Drug Class: ERYTHROPOIESIS STIMULATING AGENTS Effective 10/1/2020</td></tr>
<tr><td colspan="2">PA Required for all agents in this class*</td><td rowspan="2">*Prior Authorization is required for all products and may be approved if meeting the following:

Medication is being administered in the member’s home or in a long-term care facility AND
Member meets <u>one</u> of the following:

A diagnosis of cancer, currently receiving chemotherapy, with chemotherapy-induced anemia, and hemoglobin† of 10g/dL or lower OR
A diagnosis of chronic renal failure, and hemoglobin† below 10g/dL OR
A diagnosis of hepatitis C, currently taking Ribavirin and failed response to a reduction of Ribavirin dose, and hemoglobin† less than 10g/dL (or less than 11g/dL if symptomatic). OR
A diagnosis of HIV, currently taking Zidovudine, hemoglobin† less than 10g/dL, and serum erythropoietin level of 500mUnits/mL or less OR
Member is undergoing elective, noncardiac, nonvascular surgery and medication is given to reduce receipt of allogenic red blood cell

</td></tr>
<tr><td>RETACRIT (epoetin alfa-epbx)</td><td>ARANESP (darbepoetin alfa)

EPOGEN (epoetin alfa)

MIRCERA (methoxy peg-epoetin beta)

PROCRIT (epoetin alfa)</td></tr>
</table>

		transfusions, hemoglobin† is greater than 10g/dL, but less than or equal to 13g/dL and high risk for perioperative blood loss. Member is not willing or unable to donate autologous blood pre-operatively **AND** • For any non-preferred product, member has trialed and failed treatment with one preferred product. Failure is defined as lack of efficacy with a 6-week trial, allergy, intolerable side effects, or significant drug-drug interaction. †Hemoglobin results must be from the last 30 days.

IX. Immunological

Therapeutic Drug Class: **IMMUNE GLOBULINS** -*Effective 4/1/2020*

PA Required for all agents in this class*		
CUVITRU 20% SQ liquid GAMMAGARD 10% IV/SQ liquid GAMMAKED 10% IV/SQ liquid GAMMAPLEX 5%, 10% IV liquid GAMUNEX-C 10% IV/SQ liquid HIZENTRA 20% SQ liquid PRIVIGEN 10% IV liquid *If immune globulin is being administered in a long-term care facility or in a member's home by a home healthcare provider, it should be billed as a pharmacy claim. All other claims must be submitted through the medical benefit.*	BIVIGAM 10% IV liquid CUTAQUIG 16.5% SQ liquid FLEBOGAMMA DIF 5%, 10% IV liquid GAMMAGARD S-D solution HYQVIA 10% SQ liquid OCTAGAM 5%, 10% IV liquid PANZYGA 10% IV liquid XEMBIFY 20% IV liquid	Preferred agents may be approved for members meeting at least one of the approved conditions listed below for prescribed doses not exceeding maximum (Table 1). Non-preferred agents may be approved for members meeting the following: • Member meets at least one of the approved conditions listed below AND • Member has history of trial and failure of two preferred agents (failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions) AND • Prescribed dose does not exceed listed maximum (Table 1) <u>Approved Conditions for Immune Globulin Use</u>: • Primary Humoral Immunodeficiency disorders including: o Common Variable Immunodeficiency (CVID) o Severe Combined Immunodeficiency (SCID) o X-Linked Agammaglobulinemia o X-Linked with Hyperimmunoglobulin M (IgM) Immunodeficiency o Wiskott-Aldrich Syndrome o Members < 13 years of age with pediatric Human Immunodeficiency Virus (HIV) and CD-4 count > 200/mm3 • Neurological disorders including: o Guillain-Barré Syndrome o Relapsing-Remitting Multiple Sclerosis o Chronic Inflammatory Demyelinating Polyneuropathy o Myasthenia Gravis o Polymyositis and Dermatomyositis o Multifocal Motor Neuropathy • Chronic Lymphocytic Leukemia (CLL) • Autoimmune Neutropenia (AN) with absolute neutrophil count < 800 mm and history of recurrent bacterial infections • Autoimmune Hemolytic Anemia (AHA) • Liver or Intestinal Transplant

<table>
<tr><td></td><td></td><td>

- Immune Thrombocytopenia Purpura (ITP) including:
  - Requiring preoperative therapy for undergoing elective splenectomy with platelet count < 20,000
  - Members with active bleeding & platelet count <30,000
  - Pregnant members with platelet counts <10,000 in the third trimester
  - Pregnant members with platelet count 10,000 to 30,000 who are bleeding

<table>
<tr><th colspan="2">Table 1: FDA-Approved Maximum Immune Globulin Dosing</th></tr>
<tr><td>Gammaplex 5% - IV Infusion</td><td>800mg/kg every 3 weeks</td></tr>
<tr><td>Privigen - IV Infusion</td><td>800mg/kg every 3 weeks</td></tr>
<tr><td>Gammagard liquid - SQ or IV admin</td><td>2.4 grams/kg/month</td></tr>
<tr><td>Gammaked - SQ or IV admin</td><td>600 mg/kg every 3 weeks</td></tr>
<tr><td>Gamunex-C - SQ or IV admin</td><td>600 mg/kg every 3 weeks</td></tr>
<tr><td>Hizentra - SQ admin</td><td>0.4g/kg per week</td></tr>
<tr><td>Cuvitru - SQ admin</td><td>12.6 grams every 2 weeks</td></tr>
</table>

Grandfathering: Members currently receiving a preferred or non-preferred immunoglobulin product may receive approval to continue therapy with that product at prescribed doses not exceeding maximum (Table 1).

</td></tr>
<tr><td colspan="3">Therapeutic Drug Class: NEWER GENERATION ANTIHISTAMINES -Effective 7/1/2020</td></tr>
<tr><td>No PA Required

Cetirizine (generic OTC Zyrtec) tablet, syrup/solution

Cetirizine (RX) syrup

Levocetirizine tablet (RX/OTC)

Loratadine (generic OTC Claritin) 10mg tab and syrup</td><td>PA Required

Cetirizine (OTC) chewable tablet

CLARINEX (desloratadine)

Desloratadine

Fexofenadine

Levocetirizine (RX) solution

Loratadine chewable, ODT</td><td>Non-preferred single agent antihistamine products may be approved for members who have failed treatment with two preferred products in the last 6 months. For members with respiratory allergies, an additional trial of an intranasal corticosteroid will be required in the last 6 months.
Failure is defined as lack of efficacy with a 14 day trial, allergy, intolerable side effects, or significant drug-drug interaction.</td></tr>
<tr><td colspan="3">Therapeutic Drug Class: ANTIHISTAMINE/DECONGESTANT COMBINATIONS - Effective 7/1/2020</td></tr>
<tr><td></td><td>PA Required

Cetirizine-PSE (OTC)

CLARINEX-D (desloratadine-D)

Fexofenadine/PSE (OTC)</td><td>Non-preferred antihistamines and antihistamine/decongestant combinations may be approved for members who have failed treatment with two preferred products in the last 6 months. For members with respiratory allergies, an additional trial of an intranasal corticosteroid will be required in the last 6 months.
Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.</td></tr>
</table>

	Loratadine-D (OTC) SEMPREX-D (acrivastine-D)	
Therapeutic Drug Class: **INTRANASAL RHINITIS AGENTS** -*Effective 4/1/2020*		
No PA Required Azelastine 0.15%, 137 mcg Budesonide 32 mcg (OTC) Fluticasone 50 mcg (generic FLONASE) RX only Ipratropium Triamcinolone acetonide (generic Nasacort) (OTC)	**PA Required** ASTEPRO (azelastine) 0.15% BECONASE AQ (beclomethasone dipropionate) CHILD NASACORT (triamcinolone) DYMISTA (azelastine/ fluticasone propionate) FLONASE (fluticasone) 50 mcg (OTC) FLONASE SENSIMIST (fluticasone) 27.5 mcg (OTC) Flunisolide 0.025% Mometasone 50 mcg NASACORT AQ (triamcinolone) NASONEX (mometasone) Olopatadine 665 mcg OMNARIS (ciclesonide) PATANASE (olopatadine) QNASL (beclomethasone dipropionate) XHANCE (fluticasone propionate) ZETONNA (ciclesonide)	Non-preferred products may be approved following trial and failure of treatment with three preferred products (failure is defined as lack of efficacy with a 2 week trial, allergy, intolerable side effects or significant drug-drug interactions). Non-preferred combination agents may be approved following trial of individual products with same active ingredients AND trial and failure of one additional preferred agent (failure is defined as lack of efficacy with 2 week trial, allergy, intolerable side effects or significant drug-drug interactions).

<table>
<tr><th colspan="3">Therapeutic Drug Class: LEUKOTRIENE MODIFIERS -Effective 4/1/2020</th></tr>
<tr><th>No PA Required</th><th>PA Required</th><th></th></tr>
<tr><td>Montelukast tab, chewable</td><td>ACCOLATE (zafirlukast) tablet

SINGULAIR (montelukast) tablet, chewable tab, granules

Montelukast granules

Zafirlukast tablet

ZYFLO (zileuton ER) tablet</td><td>Non-preferred products may be approved if meeting the following criteria:
• Member has trialed and failed treatment with one preferred product (failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions) AND
• Member has a diagnosis of asthma.

Montelukast granules may be approved if a member has tried and failed montelukast chewable tablets AND has difficulty swallowing.</td></tr>
<tr><th colspan="3">Therapeutic Drug Class: METHOTREXATE PRODUCTS -Effective 1/1/2021</th></tr>
<tr><th>No PA Required</th><th>PA Required</th><th></th></tr>
<tr><td>Methotrexate tablet, vial</td><td>OTREXUP (methotrexate) auto-injector

RASUVO (methotrexate) auto-injector

TREXALL (methotrexate) tablet

XATMEP (methotrexate) oral solution</td><td>OTREXUP or RASUVO may be approved if meeting the following criteria:
• Member has diagnosis of rheumatoid arthritis AND
• Member has trialed and failed preferred methotrexate tablet formulation (failure is defined as lack of efficacy, allergy, intolerable side effects, or inability to take oral product formulation) AND
• Member is unable to administer preferred methotrexate vial formulation due to limited functional ability (such as vision impairment, limited manual dexterity and/or limited hand strength).

TREXALL may be approved if meeting the following criteria:
• Member has trialed and failed preferred methotrexate tablet formulation. Failure is defined as allergy or intolerable side effects.

XATMEP may be approved for members who meet the following criteria:
• Member is < 18 years of age
• Member has a diagnosis of acute lymphoblastic leukemia OR
• Member has a diagnosis of active polyarticular course juvenile idiopathic arthritis (pcJIA) and has had an insufficient therapeutic response to, or is intolerant to, an adequate trial of first-line therapy including full dose non-steroidal anti-inflammatory agents (NSAIDs) AND
• Member has a documented swallowing difficulty due to young age and/or a medical condition and is unable to use the preferred methotrexate tablet formulation AND
• If prescribed for a male member with reproductive potential, the member has been counseled regarding the use of contraception during therapy and for at least 3 months after the final dose OR
• If prescribed for a female member of reproductive age:
o Member has been counseled regarding use of contraception during therapy and for at least 6 months after the final dose AND
o If prescribed for a non-malignant disease indication, the member has a documented negative pregnancy test prior to initiating therapy</td></tr>
</table>

		Grandfathering: Members currently stabilized on a non-preferred methotrexate product may receive approval to continue on that agent.
Therapeutic Drug Class: **MULTIPLE SCLEROSIS AGENTS -***Effective 4/1/2020*		
Disease Modifying Therapies		
No PA Required (unless indicated*) AVONEX (interferon beta 1a) injection BETASERON (interferon beta 1b) injection COPAXONE[BNR] (glatiramer) 20MG injection *AUBAGIO (teriflunomide) tablet**2nd Line** *GILENYA[BNR] (fingolimod) 0.5 mg tablet (30-ct bottle)**2nd Line** *TECFIDERA (dimethyl fumarate) tablet BNR **2nd Line**	**PA Required** COPAXONE (glatiramer) 40MG injection Dimethyl fumarate tablet EXTAVIA (interferon beta 1b) vial GLATOPA (glatiramer) injection Glatiramer 20mg, 40mg injection GILENYA (fingolimod) 0.25 mg, 0.5 mg tablet (7-ct box) MAVENCLAD (cladribine) tablet MAYZENT (siponimod) tablet, pack PLEGRIDY (peg-interferon beta 1a) REBIF (interferon beta 1a) injection VUMERITY (diroximel) capsules	*Second-line preferred agents (**Gilenya**, **Tecfidera**, **Aubagio)** may be approved if meeting the following: • Member has documented diagnosis of multiple sclerosis made by neurologist in the last 3 years OR member has history of diagnosis made by a neurologist > 3 years ago but is naïve to all medications indicated for the treatment of relapsing forms of multiple sclerosis AND • Documentation is provided by prescribing neurologist (or name of neurologist consulted may be indicated) supporting marked functional decline as demonstrated by <u>two</u> of the following: MRI, EDSS scale, or medical chart notes supporting increased burden of disease AND • Prescriber attests to shared decision making with respect to risks versus benefits of medical treatment AND • Additional safety criteria for prescribed agent are met (Table 1). For members NOT meeting above criteria, second-line preferred agents (Gilenya, Tecfidera, Aubagio) may be approved if meeting all of the following: • Member has a diagnosis of a relapsing form of multiple sclerosis AND • Medication is being prescribed by a neurologist or in conjunction with consultation by a neurologist AND • Member has trial and failure with Copaxone OR a preferred interferon product (failure defined as intolerable side effects, drug-drug interaction, or lack of efficacy) AND • MRI results show presence of new spinal lesions, cerebellar lesions, brain stem lesions, or change in brain atrophy AND • On clinical exam, member has signs and symptoms consistent with functional limitations lasting one month or longer AND • Additional safety criteria for prescribed agent are met (Table 1). <u>Non-Preferred Products:</u> Mayzent (simponimod), Mavenclad (cladribine), and Vumerity (dioroxemel fumerate) must meet specific criteria listed for those agents below. All other non-preferred products may be approved following trial and failure with three preferred products (failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interactions). **Copaxone (glatiramer) 40mg** may be approved for members who have severe intolerable injection site reactions to <u>brand</u> Copaxone 20mg (such as pain requiring local anesthetic, oozing, lipoatrophy, swelling, or ulceration). **Mayzent (simponimod)** may be approved if meeting all of the following: • Medication is being prescribed by a neurologist or in conjunction with

		consultation by a neurologist AND • Member has a diagnosis of a relapsing form of multiple sclerosis AND • Member does not have diagnosis of macular degeneration AND • Member has baseline Expanded Disability Status Scale (EDSS) score of 3.0-6.5 AND • Member has no evidence of relapse in the 3 months preceding initiation of therapy AND • Member has previous trial and failure of Gilenya (fingolimod) therapy (failure is defined as lack of efficacy with 3-month trial, allergy, intolerable side effects, or significant drug-drug interaction) AND • Additional safety criteria for prescribed agent are met (Table 1) AND • Initial authorization will be limited to 3 months. Continuation (12-month authorization) will require documentation of EDSS reduction of 1.0 point from baseline (or reduction of 0.5 points if baseline EDSS is 5.5-6.5). **Mavenclad (cladribine)** may be approved if meeting all of the following: • Medication is being prescribed by a neurologist or in conjunction with consultation by a neurologist AND • Member has a diagnosis of a relapsing form of multiple sclerosis AND • Member has history of ≥ 1 relapse in the 12 months preceding initiation of therapy AND • Member has previous trial and failure of three other therapies for relapsing forms of multiple sclerosis (failure is defined as lack of efficacy with 3-month trial, allergy, intolerable side effects, or significant drug-drug interactions) AND • Additional safety criteria for prescribed agent are met (Table 1). **Vumerity (diroximel fumarate)** may be approved if meeting all of the following: • Medication is being prescribed by a neurologist or in conjunction with consultation by a neurologist AND • Member has a diagnosis of a relapsing form of multiple sclerosis AND • Additional safety criteria for prescribed agent are met (Table 1) AND • Member has previous trial and failure of Tecfidera (dimethyl fumarate) therapy (failure is defined as lack of efficacy with 3-month trial, allergy, intolerable side effects [if GI adverse events, must meet additional criteria below], or significant drug-drug interactions) AND • If Vumerity (diroximel fumarate) is being prescribed due to GI adverse events with Tecfidera (dimethyl fumarate) therapy (and no other reason for failure of Tecfidera is given), then the following additional criteria must be met: o Member has trialed a temporary dose reduction of Tecfidera (with maintenance dose being resumed within 4 weeks) AND o Member has trialed taking Tecfidera with food AND o GI adverse events remain significant despite maximized use of gastrointestinal symptomatic therapies (such as calcium carbonate, bismuth subsalicylate, PPIs, H2 blockers, anti-bloating/anti-constipation agents, anti-diarrheal, and centrally acting anti-emetics) AND

- Initial authorization will be limited to 3 months. Continuation (12-month authorization) will require documentation of clinically significant reduction in GI adverse events with Vumerity (diroximel fumarate) therapy.

Table 1: Safety Criteria for Select Agents	
Tecfidera (dimethyl fumarate)	• Member has no active infections AND • Member has CBC with differential conducted within the 6 months prior to initiating therapy
Aubagio (teriflunomide)	• Member has no active infections AND • For female members of child-bearing age, have negative pregnancy test at baseline and are using a highly effective form of contraceptive when appropriate (such as long-acting reversible contraception) AND • Member has transaminase and bilirubin levels with ALT < 2 times the upper limit of normal within the 6 months prior to initiating therapy AND • Member has CBC with differential conducted within the 6 months prior to initiating therapy AND • Member has a documented baseline blood pressure AND • Member has been evaluated for active or latent tuberculosis infection by documented test results (purified protein derivative test) or blood test.
Gilenya (fingolimod)	• Member has no active infections AND • Member does not have history of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or New York Heart Association Class III-IV heart failure within six months of initiating therapy AND • Member does not have a history or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome (unless patient has a pacemaker) AND • Member has a baseline QTc interval < 500 ms prior to starting therapy AND • Member is not receiving treatment with a Class Ia or Class III anti-arrhythmic medication AND • Member has had an ophthalmologic evaluation (ocular coherence test) prior to starting therapy with follow-up within 3-4 months after therapy is initiated AND • Member has had baseline CBC with differential and liver function tests conducted.
Mayzent (siponimod)	• Member does not have one of the following contraindications: ○ CYP2C9*3/*3 genotype OR ○ Has experienced (in the last 6 months) myocardial infarction, unstable angina, stroke, TIA, decompensated

			heart failure requiring hospitalization, or Class III or IV heart failure OR ○ Presence of Mobitz type II second-degree, third-degree AV block, or sick sinus syndrome (unless patient has a functioning pacemaker) AND • Member has baseline QTc interval < 500 ms prior to starting therapy AND • Member has no active infections AND • Member has not had hypersensitivity reaction to Gilenya (fingolimod) AND • Baseline CBC with differential and liver function tests are conducted prior to initiating therapy. Maximum Dose: 60mg per 30 days
		Mavenclad (cladribine)	• Member has negative pregnancy test within 30 days of request for Mavenclad AND • Men and women of childbearing potential must have plan to use effective contraception during and 6-months after therapy AND • Member does not have current evidence of malignancy AND • Member has CBC with differential drawn prior to, during, and after treatments with Mavenclad due to risk of lymphopenia and hematologic toxicity AND • Lymphocytes must be within normal limits before initiating the first treatment course and must be ≥ 800 cells per microliter before initiating the second treatment course AND • Member is not currently taking immunosuppressive or myelosuppressive therapy AND • Member has no active infections AND • Member has liver function tests drawn prior to first and second treatment course due to potential for liver injury. Maximum Dose: Not exceeding 3.5mg/kg during full treatment course
		Vumerity (diroximel fumarate)	• Member has not had hypersensitivity reaction or angioedema as a result of Tecfidera (dimethyl fumarate) therapy AND • Member has no active infections AND • A CBC with differential will be conducted within the six months prior to initiating therapy AND • Member has liver function tests drawn prior to treatment course due to potential for liver injury. Maximum Dose: 924mg per day

		Grandfathering: Members currently stabilized on a preferred second-line product or a non-preferred product may receive approval to continue therapy with that agent.
Symptom Management Therapies		
	PA Required AMPYRA ER (dalfampridine) Dalfampridine ER	**Ampyra** (dalfampridine) prior authorization for a 3-month supply may be approved if all of the following criteria are met: • Member has a diagnosis of MS; Member is ambulatory and has established a baseline which is defined as ambulating between 8-45 seconds Timed 25-foot Walk (T25FW) assessment OR has established a baseline activities of daily living (ADL) AND • Member has no history of seizure disorder AND • Member has no history of moderate to severe renal dysfunction (CrCl > 50 ml/min) AND • Prescriber is a neurologist or is prescribed in conjunction with a neurologist AND • The prescribed dose does not exceed 10 mg twice daily. Extended coverage of Ampyra (dalfampridine) for up to one year may be approved if documentation shows improvement in ambulation (measured by T25FW assessment) or improvement in ADLs after three months of therapy.
Therapeutic Drug Class: **TARGETED IMMUNE MODULATORS -***Effective 1/1/2021* *Preferred agents:* ENBREL (etanercept); HUMIRA (adalimumab); OTEZLA (apremilast) tablet; TALTZ (ixekizumab); XELJANZ IR (tofacitinib) tablet		
Rheumatoid Arthritis, Polyarticular Course Juvenile Idiopathic Arthritis, and Ankylosing Spondylitis		
No PA Required **(if diagnosis met)** **(*Must meet eligibility criteria)** ENBREL (etanercept) HUMIRA (adalimumab) *TALTZ (ixekizumab) XELJANZ IR (tofacitinib) tablet	**PA Required** ACTEMRA (tocilizumab) syringe, Actpen CIMZIA (certolizumab) kit COSENTYX (secukinumab) syringe, pen-injector ILARIS (canakinumab) vial KEVZARA (sarilumab) pen, syringe KINERET (anakinra) syringe OLUMIANT (baricitinib) tablet ORENCIA (abatacept) syringe, clickject RINVOQ (upadacitinib) tablet SIMPONI (golimumab) pen, syringe	First line preferred agents (HUMIRA, ENBREL, and XELJANZ IR) may receive approval for use for FDA-labeled indications. **Quantity Limit:** XELJANZ IR is limited to 2 tablets per day or 60 tablets for a 30 day supply ***TALTZ (ixekizumab)** may receive approval for use for FDA-labeled indications following trial and failure‡ of HUMIRA or ENBREL. **KEVZARA (sarilumab)** may receive approval for use for FDA-labeled indications following trial and failure‡ of HUMIRA or ENBREL **AND** XELJANZ IR. **KINERET (anakinra)** may receive approval for use for FDA-labeled indications following trial and failure‡ of HUMIRA or ENBREL **AND** XELJANZ IR. All other non-preferred agents may receive approval for FDA-labeled indications following trial and failure‡ of all indicated first line preferred agents (HUMIRA, ENBREL, and XELJANZ IR). Agents listed below must meet the following additional criteria for approval of that agent: **XELJANZ (tofacitinib) XR** approval will require verification of the clinically relevant reason for use of the XELJANZ XR formulation versus the XELJANZ IR formulation, in addition to meeting non-preferred criteria listed above.

	XELJANZ XR (tofacitinib ER) tablet ***for information on IV infused Targeted Immune Modulators please see Appendix P**	‡Failure is defined as lack of efficacy with a three-month trial, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction. **Grandfathering:** Members with current prior authorization approval on file for COSENTYX may receive approval to continue on that agent. *The Department would like to remind providers that many products are associated with patient-centered programs that are available to assist with drug administration, education, and emotional support related to our members' various disease states.*
Psoriatic Arthritis		
No PA Required (if diagnosis met) (*Must meet eligibility criteria) ENBREL (etanercept) HUMIRA (adalimumab) *OTEZLA (apremilast) tablet *TALTZ (ixekizumab) XELJANZ IR (tofacitinib) tablet	**PA Required** CIMZIA (certolizumab) kit COSENTYX (secukinumab) syringe, pen-injector ORENCIA (abatacept) syringe, clickject SIMPONI (golimumab) pen, syringe STELARA (ustekinumab) syringe TREMFYA (guselkumab) injector, syringe XELJANZ XR (tofacitinib ER) tablet ***for information on IV infused Targeted Immune Modulators please see Appendix P**	First line preferred agents (HUMIRA, ENBREL, XELJANZ IR) may receive approval for psoriatic arthritis indication. **Quantity Limit:** XELJANZ IR is limited to 2 tablets per day or 60 tablets for a 30 day supply *TALTZ may receive approval for psoriatic arthritis indication following trial and failure‡ of HUMIRA or ENBREL **AND** XELJANZ IR or OTEZLA. *OTEZLA may receive approval for psoriatic arthritis indication following trial and failure‡ of HUMIRA or ENBREL **AND** XELJANZ IR or TALTZ. Non-preferred agents may receive approval for psoriatic arthritis following trial and failure‡ of HUMIRA or ENBREL AND XELJANZ IR AND TALTZ or OTEZLA. Agents listed below must meet the following additional criteria for approval of that agent: **STELARA (ustekinumab):** Loading dose administration prior to approval of STELARA for maintenance therapy using the above criteria should be avoided and will not result in an automatic approval of STELARA maintenance therapy. Prior authorization approval may be given for an initial 16 weeks and authorization approval for continuation may be provided based on clinical response. STELARA IV vial formulation may receive approval under the pharmacy benefit if meeting non-preferred criteria listed above AND if being administered in a long-term care facility or the member's home by a home health provider (initial 16 week authorization may be placed for both IV and subcutaneous formulations at time of Stelara IV vial approval). **XELJANZ (tofacitinib) XR** approval will require verification of the clinically relevant reason for use of the XELJANZ XR formulation versus the XELJANZ IR formulation, in addition to meeting non-preferred criteria listed above. ‡Failure is defined as lack of efficacy with a three-month trial, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction. **Grandfathering:** Members with current prior authorization approval on file for COSENTYX may receive approval to continue on that agent.

		The Department would like to remind providers that many products are associated with patient-centered programs that are available to assist with drug administration, education, and emotional support related to our members' various disease states.
Plaque Psoriasis		
No PA Required (if diagnosis met) (*Must meet eligibility criteria) ENBREL (etanercept) HUMIRA (adalimumab) *OTEZLA (apremilast) tablet *TALTZ (ixekizumab)	**PA Required** CIMZIA (certolizumab) kit COSENTYX (secukinumab) syringe, pen-injector SILIQ (brodalumab) syringe SKYRIZI (risankizumab-rzaa) syringe, kit STELARA (ustekinumab) syringe TREMFYA (guselkumab) injector, syringe ***for information on IV infused Targeted Immune Modulators please see Appendix P**	First line preferred agents (HUMIRA, ENBREL) may receive approval for plaque psoriasis indication. *Second line preferred agents (TALTZ, OTEZLA) may receive approval for plaque psoriasis indication following trial and failure‡ of HUMIRA OR ENBREL. Non-preferred agents may receive approval for plaque psoriasis indication following trial and failure‡ of one indicated first line agent (HUMIRA, ENBREL) AND two second line agents (TALTZ, OTEZLA). Agents listed below must meet the following additional criteria for approval of that agent: **STELARA (ustekinumab):** Loading dose administration prior to approval of STELARA for maintenance therapy using the above criteria should be avoided and will not result in an automatic approval of STELARA maintenance therapy. Prior authorization approval may be given for an initial 16 weeks and authorization approval for continuation may be provided based on clinical response. STELARA IV vial formulation may receive approval under the pharmacy benefit if meeting non-preferred criteria listed above AND if being administered in a long-term care facility or the member's home by a home health provider (initial 16 week authorization may be placed for both IV and subcutaneous formulations at time of STELARA IV vial approval). ‡Failure is defined as lack of efficacy with a three-month trial, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction. **Grandfathering:** Members with current prior authorization approval on file for COSENTYX may receive approval to continue on that agent. *The Department would like to remind providers that many products are associated with patient-centered programs that are available to assist with drug administration, education, and emotional support related to our members' various disease states.*
Crohn's Disease and Ulcerative Colitis		
No PA Required (if diagnosis met) (*Must meet eligibility criteria) HUMIRA (adalimumab) *XELJANZ IR (tofacitinib) tablet	**PA Required** CIMZIA (certolizumab) kit SIMPONI (golimumab) pen, syringe STELARA (ustekinumab) syringe XELJANZ XR (tofacitinib ER) tablet	First line preferred agents (HUMIRA) may receive approval for Crohn's disease and ulcerative colitis indications. *XELJANZ IR may receive approval for ulcerative colitis indication following trial and failure† of HUMIRA. **Quantity Limit:** XELJANZ IR is limited to 2 tablets per day or 60 tablets for a 30 day supply

	***for information on IV infused Targeted Immune Modulators please see Appendix P**	Non-preferred agents may receive approval for FDA-labeled indications following trial and failure† of all indicated preferred agents. Agents listed below must meet the following additional criteria for approval of that agent: **STELARA (ustekinumab):** STELARA (ustekinumab): Loading dose administration prior to approval of STELARA for maintenance therapy using the above criteria should be avoided and will not result in an automatic approval of STELARA maintenance therapy. STELARA may be approved for treatment of moderately-to-severely active Crohn's disease following trial and failure† of all indicated preferred agents (HUMIRA) AND CIMZIA. STELARA may be approved for moderately-to-severely active ulcerative colitis following trial and failure† of all indicated preferred agents (HUMIRA and XELJANZ IR). Prior authorization approval may be given for an initial 16 week supply and authorization approval for continuation may be provided based on clinical response. STELARA IV vial formulation may receive approval under the pharmacy benefit if meeting non-preferred criteria listed above AND if being administered in a long-term care facility or the member's home by a home health provider (initial 16 week authorization may be placed for both IV and subcutaneous formulations at time of STELARA IV vial approval). **XELJANZ (tofacitinib) XR** approval will require verification of the clinically relevant reason for use of the XELJANZ XR formulation versus the XELJANZ IR formulation, in addition to meeting non-preferred criteria listed above. †Failure is defined as lack of efficacy with a three-month trial, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction. Note that trial and failure of Xeljanz IR will not be required when prescribed for ulcerative colitis for members ≥ 50 years of age that have an additional CV risk factor. *The Department would like to remind providers that many products are associated with patient-centered programs that are available to assist with drug administration, education, and emotional support related to our members' various disease states.*
Other indications		
Must meet eligibility criteria* ENBREL (etanercept) HUMIRA (adalimumab) *OTEZLA (apremilast) tablet *TALTZ (ixekizumab) XELJANZ IR (tofacitinib) tablet	**PA Required** ACTEMRA (tocilizumab) syringe, Actpen ARCALYST (rilonacept) injection CIMZIA (certolizumab) kit COSENTYX (secukinumab) syringe, pen-injector ILARIS (canakinumab) vial	First line preferred agents (HUMIRA, ENBREL, and XELJANZ IR) may receive approval for use for FDA-labeled indications. **Quantity Limit:** XELJANZ IR is limited to 2 tablets per day or 60 tablets for a 30 day supply Second-line preferred agents may receive approval for FDA-labeled indications following trial and failure‡ of all indicated first-line preferred agents (ENBREL, HUMIRA, XELJANZ IR). Non-preferred agents may receive approval for FDA-labeled indications following trial and failure‡ of all indicated preferred agents (ENBREL, HUMIRA, XELJANZ IR, Taltz, Otezla). Agents listed below must meet the following additional criteria for approval of that agent:

	KINERET (anakinra) syringe ***for information on IV infused Targeted Immune Modulators please see Appendix P**	**ARCALYST (rilonacept)** may receive approval if meeting the following: • Medication is being prescribed for one of the following autoinflammatory periodic fever syndromes (approval for all other indications is subject to meeting non-preferred criteria listed above): o Adult-Onset Still's Disease (AOSD) o Cryopyrin-associated Autoinflammatory Syndrome (CAPS), including: ▪ Familial Cold Autoinflammatory Syndrome (FCAS) ▪ Muckle-Wells Syndrome (MWS) **AND** • Member has trialed and failed‡ colchicine **AND** • Initial approval will be given for 12 weeks and authorization approval for continuation will be provided based on clinical response. **ILARIS (canakinumab)** may receive approval if meeting the following: • Medication is being prescribed for one of the following autoinflammatory periodic fever syndromes (approval for all other indications is subject to meeting non-preferred criteria listed above): o Adult onset Still's Disease (AOSD) o Familial Mediterranean Fever (FMF) o Hyperimmunoglobulinemia D syndrome (HIDS) o Mevalonate Kinase Deficiency (MKD) o Neonatal onset multisystem inflammatory disease (NOMID) o Systemic Juvenile Idiopathic Arthritis (sJIA) o TNF Receptor Associated Periodic Syndrome (TRAPS) o Cryopyrin-associated Autoinflammatory Syndrome (including Familial Cold Autoinflammatory Syndrome and Muckle-Wells Syndrome) **AND** • Member has trialed and failed‡ colchicine. **KINERET (anakinra)** may receive approval if meeting the following: • Medication is being prescribed for one of the following indications (approval for all other indications is subject to meeting non-preferred criteria above): o Neonatal onset multisystem inflammatory disease (NOMID). o Familial Mediterranean Fever (FMF) **AND** • Member has trialed and failed‡ colchicine. ‡Failure is defined as lack of efficacy with a three-month trial, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction. **Grandfathering:** Members with current prior authorization approval on file for COSENTYX may receive approval to continue on that agent. *The Department would like to remind providers that many products are associated with patient-centered programs that are available to assist with drug administration, education, and emotional support related to our members' various disease states.*

X. Miscellaneous

Therapeutic Drug Class: **EPINEPHRINE PRODUCTS** -*Effective 1/1/2021*

No PA Required	**PA Required**	
Epinephrine 0.15mg/0.3ml, 0.3mg/0.3ml auto-injector (generic Epipen) -*Mylan only*-	EPIPEN 0.3mg/0.3ml (epinephrine) auto-injector EPIPEN JR 0.15mg/0.3ml, (epinephrine) auto-injector Epinephrine 0.15mg/0.15ml, 0.3mg/0.3ml auto-injector (generic Adrenaclick) Epinephrine 0.15mg/0.15ml, 0.3mg/0.3ml auto-injector (generic Epipen) -*Teva only*- SYMJEPI 0.15mg/0.3ml, 0.3mg/0.3ml (epinephrine) syringe	Non-preferred products will be approved if the member has failed treatment with one of the preferred products. Failure is defined as allergy to ingredients in product or intolerable side effects. Quantity limit: 4 auto injectors per year unless used / damaged / lost

Therapeutic Drug Class: **NEWER HEREDITARY ANGIOEDEMA PRODUCTS** -*Effective 10/1/2020*

PA Required for all agents in this class		
Prophylaxis: HAEGARDA (C1 esterase inhibitor) vial *Treatment:* BERINERT (C1 esterase inhibitor) kit FIRAZYR[BNR] (icatibant acetate) syringe	*Prophylaxis:* CINRYZE (C1 esterase inhibitor) kit TAKHZYRO (lanadelumab-flyo) vial *Treatment:* Icatibant syringe RUCONEST (C1 esterase inhibitor, recomb) vial	Medications Indicated for Routine Prophylaxis: Members are restricted to coverage of one medication for routine prophylaxis at one time. Prior authorization approval will be for one year. **HAEGARDA** (C1 esterase inhibitor (human)) may be approved for members meeting the following criteria: o Member has a diagnosis of HAE confirmed by laboratory tests obtained on two separate instances at least one month apart (C4 level, CI-INH level) **AND** o Member has a documented history of at least one symptom of a moderate to severe HAE attack (moderate to severe abdominal pain, facial swelling, airway swelling) in the absence of hives or a medication known to cause angioedema AND o Member meets at least one of the following: ▪ Haegarda® is being used for short-term prophylaxis to undergo a surgical procedure or major dental work **OR** ▪ Haegarda® is being used for long-term prophylaxis and member meets one of the following: o History of ≥1 attacks per month resulting in documented ED admission or hospitalization **OR** o History of laryngeal attacks **OR** o History of ≥2 attacks per month involving the face, throat, or abdomen **AND**

		○ Member is not taking medications that may exacerbate HAE including ACE inhibitors and estrogen-containing medications **AND** ○ Member has received hepatitis A and hepatitis B vaccination **AND** ○ Provider attests to performing annual testing or screening (as appropriate) for HBV, HCV, and HIV Maximum Dose: 60 IU/kg Minimum Age: 10 years **CINRYZE** (C1 esterase inhibitor (human)) may be approved for members meeting the following criteria: ○ Member has history of trial and failure of Haegarda®. Failure is defined as lack of efficacy allergy, intolerable side effects, or a significant drug-drug interaction **AND** ○ Member has a diagnosis of HAE confirmed by laboratory tests obtained on two separate instances at least one month apart (C4 level, CI-INH level) **AND** ○ Member has a documented history of at least one symptom of a moderate to severe HAE attack (moderate to severe abdominal pain, facial swelling, airway swelling) in the absence of hives or a medication known to cause angioedema AND ○ Member meets at least one of the following: ▪ Cinryze® is being used for <u>short-term prophylaxis</u> to undergo a surgical procedure or major dental work **OR** ▪ Cinryze® is being used for <u>long-term prophylaxis</u> and member meets one of the following: ○ History of ≥1 attacks per month resulting in documented ED admission or hospitalization **OR** ○ History of laryngeal attacks **OR** ○ History of ≥2 attacks per month involving the face, throat, or abdomen **AND** ○ Member is not taking medications that may exacerbate HAE including ACE inhibitors and estrogen-containing medications **AND** ○ Member has received hepatitis A and hepatitis B vaccination **AND** ○ Provider attests to performing annual testing or screening (as appropriate) for HBV, HCV, and HIV. Minimum age: 6 years Maximum dose: 100 Units/kg **TAKHZYRO** (lanadelumab-flyo) may be approved for members meeting the following criteria: ○ Member has history of trial and failure of Haegarda. Failure is defined as: lack of efficacy, allergy, intolerable side effects, or a significant drug-drug interaction **AND** ○ Member has a diagnosis of HAE confirmed by laboratory tests obtained on two separate instances at least one month apart (C4 level, CI-INH level) **AND** ○ Member has a documented history of at least one symptom of a moderate to severe HAE attack (moderate to severe abdominal pain, facial swelling, airway swelling) in the absence of hives or a medication known to cause angioedema **AND**

		○ Member is not taking medications that may exacerbate HAE including ACE inhibitors and estrogen-containing medications **AND** ○ Member has received hepatitis A and hepatitis B vaccination. Minimum age: 12 years Maximum dose: The recommended starting dose is 300mg every 2 weeks. A dosing interval of 300 mg every 4 weeks is also effective and may be considered if the patient is well-controlled (attack free) for more than 6 months **Medications Indicated for Treatment of Acute Attacks:** Members are restricted to coverage of one medication for treatment of acute attacks at one time. Prior authorization approval will be for one year. **FIRAZYR** (icatibant acetate) may be approved for members meeting the following criteria: ○ Member has a diagnosis of HAE confirmed by laboratory tests obtained on two separate instances at least one month apart (C4 level, CI-INH level) **AND** ○ Member has a documented history of at least one symptom of a moderate to severe HAE attack (moderate to severe abdominal pain, facial swelling, airway swelling) in the absence of hives or a medication known to cause angioedema AND ○ Member is not taking medications that may exacerbate HAE including ACE inhibitors and estrogen-containing medications Minimum age: 18 years Maximum dose: 30mg **BERINERT** (C1 esterase inhibitor (human)) may be approved for members meeting the following criteria: ○ Member has a diagnosis of HAE confirmed by laboratory tests obtained on two separate instances at least one month apart (C4 level, CI-INH level) **AND** ○ Member has a documented history of at least one symptom of a moderate to severe HAE attack (moderate to severe abdominal pain, facial swelling, airway swelling) in the absence of hives or a medication known to cause angioedema AND ○ Member is not taking medications that may exacerbate HAE including ACE inhibitors and estrogen-containing medications **AND** ○ Member has received hepatitis A and hepatitis B vaccination **AND** ○ Provider attests to performing annual testing or screening (as appropriate) for HBV, HCV, and HIV Minimum age: 6 years Max dose: 20 IU/kg **RUCONEST** (C1 esterase inhibitor (recombinant)) may be approved for members meeting the following criteria:

		○ Member has a history of trial and failure of Firazyr® OR Berinert®. Failure is defined as lack of efficacy, allergy, intolerable side effects, or a significant drug-drug interaction **AND** ○ Member has a diagnosis of HAE confirmed by laboratory tests obtained on two separate instances at least one month apart (C4 level, CI-INH level) **AND** ○ Member has a documented history of at least one symptom of a moderate to severe HAE attack (moderate to severe abdominal pain, facial swelling, airway swelling) in the absence of hives or a medication known to cause angioedema AND ○ Member is not taking medications that may exacerbate HAE including ACE inhibitors and estrogen-containing medications **AND** ○ Member has received hepatitis A and hepatitis B vaccination **AND** ○ Provider attests to performing annual testing or screening (as appropriate) for HBV, HCV, and HIV. Minimum age: 13 years Maximum dose: 4200 Units/dose All other non-preferred agents may be approved if the member has trialed and failed at least two preferred agents with the same indicated role in therapy as the prescribed medication (prophylaxis or treatment). Failure is defined as lack of efficacy, allergy, intolerable side effects, or a significant drug-drug interaction.
Therapeutic Drug Class: **PHOSPHATE BINDERS** -*Effective 7/1/2020*		
No PA Required Calcium acetate capsule PHOSLYRA (calcium acetate) Sevelamer carbonate tablet (6-17 years old)* Sevelamer HCl *authorized generic* - *WINTHROP US only* -	**PA Required** AURYXIA (ferric citrate) Calcium acetate tablet CALPHRON (calcium acetate) FOSRENOL (lanthanum carbonate) chewable tablet, powder pack Lanthanum carbonate chewable tablet, powder pack RENAGEL (Sevelamer HCl) RENVELA (sevelamer carbonate) Sevelamer carbonate powder pack	Prior authorization for non-preferred products in this class may be approved if member meets all the following criteria: ● Member has diagnosis of end stage renal disease AND ● Member has elevated serum phosphorus [> 4.5 mg/dL or > 1.46 mmol/L] AND ● Provider attests to member avoidance of high phosphate containing foods from diet AND ● Member has trialed and failed‡ one preferred agent (lanthanum products require trial and failure‡ of a preferred sevelamer product). **Auryxia** (ferric citrate) may be approved if the member meets all the following criteria: ● Member is diagnosed with end-stage renal disease, receiving dialysis, and has elevated serum phosphate (> 4.5 mg/dL or > 1.46 mmol/L). AND ● Provider attests to counseling member regarding avoiding high phosphate containing foods from diet AND ● Member has trialed and failed‡ three preferred agents with different mechanisms of action prescribed for hyperphosphatemia in end stage renal disease OR ● Member is diagnosed with chronic kidney disease with iron deficiency anemia and is not receiving dialysis AND ● Member has tried and failed‡ at least two different iron supplement product formulations (OTC or RX)

	Sevelamer HCl tablet -*all other manufacturers* VELPHORO (sucroferric oxide)	**Velphoro** (sucroferric oxyhydroxide tablet, chewable) may be approved if the member meets all of the following criteria: • Member is diagnosed with chronic kidney disease and receiving dialysis, and has elevated serum phosphate (> 4.5 mg/dL or > 1.46 mmol/L). AND • Provider attests to counseling member regarding avoiding high phosphate containing foods from diet AND • Member has trialed and failed‡ two preferred agents, one of which must be a preferred sevelamer product Maximum Dose: Velphoro 3000mg daily Grandfathering: Members currently stabilized on a non-preferred lanthanum product may receive approval to continue therapy with that product. ‡Failure is defined as lack of efficacy with 6 week trial, allergy, intolerable side effects, or significant drug-drug interaction. *Note: Medications administered in a dialysis unit or clinic are billed through the Health First Colorado medical benefit or Medicare with members with dual eligibility.*
Therapeutic Drug Class: **PRENATAL VITAMINS / MINERALS** -*Effective 10/1/2020*		
***Must meet eligibility criteria** *Manufacturer participation changes, effective 1/1/2021* COMPLETE NATAL DHA M-NATAL PLUS NESTABS tablets PNV 29-1 tablet PRENATAL VITAMIN PLUS LOW IRON PREPLUS tablet PROVIDA OB capsule THRIVITE RX tablet TRINATAL RX 1 TRUST NATAL DHA	**PA Required** All other rebateable prescription products are non-preferred	*Preferred and non-preferred prenatal vitamin products are a benefit for members from 11-60 years of age who are pregnant, lactating, or trying to get pregnant. Prior authorization for non-preferred agents may be approved if member fails 7-day trial with four preferred agents. Failure is defined as: allergy, intolerable side effects, or significant drug-drug interaction.

VITAFOL gummies VOL-PLUS tablet		

XI. Ophthalmic

Therapeutic Drug Class: **OPHTHALMIC, ALLERGY** -*Effective 4/1/2020*		
No PA Required	**PA Required**	Non-preferred products may be approved following trial and failure of therapy with two preferred products (failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions).
ALREX (loteprednol) 2% Cromolyn 4% Ketotifen (generic Zaditor) 0.025% (OTC) LASTACAFT (alcaftadine) 0.25% Olopatadine 0.1%, 0.2% PAZEO (olopatadine) 0.7%	ALAWAY (ketotifen) 0.025% ALOCRIL (nedocromil) 2% ALOMIDE (lodoxamide) 0.1% Azelastine 0.05% BEPREVE (bepotastine) 1.5% Epinastine 0.05% PATADAY (olopatadine) 0.2% PATANOL (olopatadine) 0.1% ZADITOR (ketotifen) 0.025% (OTC)	

Therapeutic Drug Class: **OPHTHALMIC, IMMUNOMODULATORS** -*Effective 10/1/2020*		
No PA Required	**PA Required**	Non-preferred products may be approved for members meeting all of the following criteria: ● Member is 18 years and older **AND** ● Member has a diagnosis of chronic dry eye **AND** ● Member has failed a 3-month trial of one preferred product. Failure is defined as a lack of efficacy, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions **AND** ● Prescriber is an ophthalmologist, optometrist or rheumatologist <u>Maximum Dose/Quantity:</u> 60 single use containers for 30 days 5.5 mL/20 days for Restasis Multi-Dose
RESTASIS (cyclosporine 0.05%)	CEQUA (cyclosporine 0.09%) solution RESTASIS MULTIDOSE (cyclosporine 0.05%) XIIDRA (lifitegrast)	

Therapeutic Drug Class: **OPHTHALMIC, ANTI-INFLAMMATORIES** -*Effective 4/1/2020*

NSAIDs

No PA Required	PA Required
ACUVAIL (ketorolac)	ACULAR (ketorolac) 0.5%, LS 0.4%
Bromfenac 0.09%	BROMSITE (bromfenac) 0.075%
Diclofenac 0.1%	ILEVRO (nepafenac) 0.03%
Flurbiprofen 0.03%	NEVANAC (nepafenac) 0.1%
Ketorolac 0.5%, Ketorolac LS 0.4%	PROLENSA (bromfenac) 0.07%

Corticosteroids

No PA Required	PA Required
FLAREX (fluorometholone) 0.1%	Dexamethasone 0.1%
Fluorometholone 0.1% drops	DUREZOL (difluprednate) 0.05%
FML Forte (fluorometholone) 0.25% drops	FML LIQUIFILM (fluorometholone) 0.1% drop
LOTEMAX (loteprednol) 0.5% drops[BNR], 0.5% ointment	FML S.O.P (fluorometholone) 0.1% ointment
MAXIDEX (dexamethasone) 0.1%	INVELTYS (loteprednol) 1%
PRED MILD (prednisolone) 0.12%	LOTEMAX (loteprednol) 0.5% gel
Prednisolone acetate 1%	LOTEMAX SM (loteprednol) 0.38% gel
	Loteprednol 0.5% drops
	OMNIPRED (prednisolone) 1%
	PRED FORTE (prednisolone) 1%
	Prednisolone sodium phosphate 1%

Non-preferred products may be approved with trial and failure of three preferred agents (failure is defined as lack of efficacy with 2-week trial, allergy, contraindication, intolerable side effects, or significant drug-drug interaction).

Durezol may be approved if meeting the following criteria:

- Member has a diagnosis of severe intermediate uveitis, severe panuveitis, or severe uveitis with the complication of uveitic macular edema AND has trialed and failed at least a 2 week trial of prednisolone acetate 1% (failure is defined as lack of efficacy with 2 week trial, allergy, contraindication, intolerable side effects, or significant drug-drug interaction) OR
- Members with a diagnosis other than those listed above require trial and failure of three preferred agents (failure is defined as lack of efficacy with 2-week trial, allergy, contraindication, intolerable side effects, or significant drug-drug interaction).

Lotemax SM (loteprednol etabonate) may be approved if meeting all of the following:

- Member is ≥18 years of age AND
- Lotemax SM (loteprednol etabonate) is being used for the treatment of post-operative inflammation and pain following ocular surgery AND
- Member has trialed and failed therapy with two preferred loteprednol formulations (failure is defined as lack of efficacy with 2-week trial, allergy, contraindication, intolerable side effects, or significant drug-drug interaction) AND
- Member has trialed and failed therapy with two preferred agents that do not contain loteprednol (failure is defined as lack of efficacy with 2-week trial, allergy, contraindication, intolerable side effects, or significant drug-drug interaction) AND
- Member does not have any of the following conditions:
  - Viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella OR
  - Mycobacterial infection of the eye and fungal diseases of ocular structures

Therapeutic Drug Class: **OPHTHALMIC, GLAUCOMA -***Effective 4/1/2020*

Beta-blockers

No PA Required	PA Required
Levobunolol	BETAGAN (levobunolol)
Timolol (generic Timoptic)	Betaxolol
	BETOPIC-S (betaxolol)
	Carteolol
	ISTALOL (timolol)
	Timolol (generic Istalol) drops
	Timolol GFS
	TIMOPTIC, TIMOPTIC OCUDOSE (timolol)
	TIMOPTIC-XE (timolol GFS)

Carbonic anhydrase inhibitors

No PA Required	PA Required
AZOPT (brinzolamide) BNR	Brinzolamide (generic Azopt)
Dorzolamide	TRUSOPT (dorzolamide)

Prostaglandin analogue

No PA Required	PA Required
Latanoprost	Bimatoprost
LUMIGAN BNR (bimatoprost)	Latanoprost PF
TRAVATAN Z BNR (travoprost)	VYZULTA (latanoprostene)
	XALATAN (latanoprost)
	XELPROS (latanoprost)

Non-preferred products may be approved following trial and failure of therapy with three preferred products, including one trial with a preferred product having the same general mechanism (such as prostaglandin analogue, alpha2-adrenergic agonist, beta-blocking agent, or carbonic anhydrase inhibitor). Failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions.

Non-preferred combination products may be approved following trial and failure of therapy with one preferred combination product AND trial and failure of individual products with the same active ingredients as the combination product being requested (if available) to establish tolerance. Failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions.

Preservative free products may be approved with provider documentation of adverse effect to preservative-containing product.

	ZIOPTAN (tafluprost PF)	
Alpha-2 adrenergic agonists		
No PA Required	**PA Required**	
ALPHAGAN P 0.1% (brimonidine)	Apraclonidine	
ALPHAGAN P[BNR] 0.15% (brimonidine)	Brimonidine 0.15%	
Brimonidine 0.2%	IOPIDINE (apraclonidine)	
Other ophthalmic, glaucoma and combinations		
No PA Required	**PA Required**	
COMBIGAN (brimonidine/timolol)	COSOPT PF (dorzolamide/timolol)	
Dorzolamide/Timolol	Echothiopate iodide	
Dorzolamide/Timolol PF	PHOSPHOLINE IODIDE (echothiophate)	
	Pilocarpine	
	RHOPRESSA (netarsudil)	
	ROCKLATAN (netarsudil/latanoprost)	
	SIMBRINZA (brinzolamide/brimonidine)	

XII. Renal/Genitourinary

Therapeutic Drug Class: **BENIGN PROSTATIC HYPERPLASIA (BPH)** -*Effective 7/1/2020*		
No PA Required	**PA Required**	
Alfuzosin ER tablet	AVODART (dutasteride)	Prior authorization for non-preferred products in this class may be approved if member meets all of the following criteria: ● Member has tried and failed‡ three preferred agents AND ● For combinations agents, member has tried and failed‡ each of the individual agents within the combination agent and one other preferred agent. ‡Failure is defined as lack of efficacy with 8-week trial, allergy, intolerable side effects, contraindication to, or significant drug-drug interaction.
Doxazosin tablet	CARDURA (doxazosin)	
Dutasteride capsule	CARDURA XL (doxazosin ER)	
Finasteride tablet	*CIALIS (tadalafil) 2.5 mg, 5 mg	

Tamsulosin capsule Terazosin capsule	Dutasteride/tamsulosin FLOMAX (tamsulosin) JALYN (dutasteride/tamsulosin) PROSCAR (finasteride) RAPAFLO (silodosin) Silodosin capsule *Tadalafil 2.5 mg, 5 mg	***Cialis** will be approved for members with a documented diagnosis of BPH who have failed a trial of finasteride (at least 3 months in duration) AND either a trial of a nonselective alpha blocker (therapeutic dose for at least two months) OR a trial of tamsulosin (therapeutic dose for at least one month). Documentation of BPH diagnosis will require BOTH of the following: ● AUA Prostate Symptom Score ≥ 8 AND ● Results of a digital rectal exam. Cialis will not be approved for any patient continuing alpha-blocker therapy as this combination is contraindicated in this population. Doses exceeding 5mg per day of Cialis will not be approved.
Therapeutic Drug Class: **ANTI-HYPERURICEMICS -***Effective 1/1/2021*		
No PA Required Allopurinol tablet MITIGARE[BNR] (colchicine) capsule Probenecid tablet Probenecid/Colchicine tablet	**PA Required** Colchicine capsule, tablet COLCRYS (colchicine) tablet Febuxostat tablet GLOPERBA (colchicine) oral solution ULORIC (febuxostat) tablet ZYLOPRIM (allopurinol) tablet	Non-preferred xanthine oxidase inhibitor products (allopurinol or febuxostat formulations) may be approved following trial and failure of preferred allopurinol. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. If member has tested positive for the HLA-B*58:01 allele, it is not recommended that they trial allopurinol. A positive result on this genetic test will count as a failure of allopurinol. Prior authorization for all other non-preferred agents (non-xanthine oxidase inhibitors) may be approved after trial and failure of two preferred products. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. **GLOPERBA (colchicine)** oral solution may be approved for members who require individual doses <0.6 mg OR for members who have documented swallowing difficulty due to young age and/or a medical condition (preventing use of solid oral dosage form). Prior authorization for colchicine tablets may be approved for members requiring treatment of gout flares. Colchicine tablet quantity limits: • Chronic hyperuricemia/gout prophylaxis: 60 tablets per 30 days • Familial Mediterranean Fever: 120 tablets per 30 days
Therapeutic Drug Class: **OVERACTIVE BLADDER AGENTS -***Effective 10/1/2020*		
No PA Required GELNIQUE (oxybutynin) gel Oxybutynin IR, ER tablets, syrup Oxybutynin ER tablets	**PA Required** Darifenacin ER tablet DETROL (tolterodine) DETROL LA (tolterodine ER)	Non-preferred products may be approved for members who have failed treatment with two preferred products. Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. Members with hepatic failure can receive approval for trospium (Sanctura) or trospium extended release (Sanctura XR) products without a trial on a Preferred product.

Solifenacin tablet TOVIAZ (fesoterodine ER)	DITROPAN (brand) DITROPAN XL (brand) ENABLEX (darifenacin) Flavoxate GELNIQUE (oxybutynin) gel pump MYRBETRIQ (mirabegron) OXYTROL (oxybutynin patch) SANCTURA (trospium) SANCTURA XL (trospium ER) Tolterodine Trospium ER capsule, tablet VESICARE (solifenacin)	

XIII. RESPIRATORY

Therapeutic Drug Class: **RESPIRATORY INHALANTS** -*Effective 7/1/2020*

Inhaled Anticholinergics

No PA Required	**PA Required**	
<u>Solutions</u> Ipratropium (generic Atrovent) solution **<u>Short-Acting Inhalers</u>** ATROVENT HFA (ipratropium) **<u>Long-Acting Inhalers</u>** SPIRIVA Handihaler (tiotropium)	**<u>Solutions</u>** ATROVENT (ipratropium) solution LONHALA Magnair (glycopyrrolate) solution YUPELRI (revefenacin) solution **<u>Short-Acting Inhalers</u>** **<u>Long-Acting Inhalers</u>** INCRUSE ELLIPTA (umeclidinium)	Non-preferred single agent anticholinergic agents may be approved for members with a diagnosis of COPD including chronic bronchitis and/or emphysema who have trialed and failed‡ treatment with two preferred agents, one of which must be Spiriva Handihaler. **Spiriva Respimat** may be approved for members with a diagnosis of asthma who have trialed and failed‡ treatment with three preferred inhaled corticosteroids, at least two of the trials must be preferred combination inhaled corticosteroid products. Members with a diagnosis of COPD must meet non-preferred criteria for single agent inhaled anticholinergics listed above for approval of Spiriva Respimat®. **Lonhala Magnair** may be approved for members ≥ 18 years of age with a diagnosis of COPD including chronic bronchitis and emphysema who have trialed and failed‡ treatment with two preferred anticholinergic agents.

	SEEBRI Neohaler (glycopyrrolate) SPIRIVA RESPIMAT (tiotropium) TUDORZA Pressair (aclidinium)	‡Failure is defined as lack of efficacy with 6 week trial, allergy, intolerable side effects, or significant drug-drug interaction.
Inhaled Anticholinergic Combinations		
No PA Required **Solutions** Albuterol/ipratropium solution **Short-Acting Inhalers** COMBIVENT RESPIMAT (albuterol/ipratropium) **Long-Acting Inhalers** BEVESPI AEROSPHERE (glycopyrrolate/formoterol fumarate)	**PA Required** **Solutions** **Short-Acting Inhalers** **Long-Acting Inhalers** ANORO ELLIPTA (umeclidinium/vilanterol) DUAKLIR Pressair (aclidinium/formoterol) STIOLTO Respimat (tiotropium/olodaterol) UTIBRON Neohaler (glycopyrrolate/indacaterol)	Non-preferred inhaled anticholinergic combination agents may be approved for members with a diagnosis of COPD including chronic bronchitis and/or emphysema who have trialed and failed‡ treatment with two preferred inhaled anticholinergic combination agents. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. ‡Failure is defined as lack of efficacy with 6 week trial, allergy, intolerable side effects, or significant drug-drug interaction.
Inhaled Beta2 Agonists (short acting)		
No PA Required **Solutions** Albuterol (generic) solution **Inhalers** PROAIR (albuterol) HFA BNR VENTOLIN (albuterol) HFA inhaler BNR	**PA Required** **Solutions** Levalbuterol solution PROVENTIL (albuterol) solution XOPENEX (levalbuterol) solution **Inhalers** Albuterol HFA Levalbuterol HFA PROAIR Digihaler, Respiclick (albuterol) PROVENTIL (albuterol) HFA inhaler	Non-preferred, short acting beta2 agonists will be approved for members who have failed treatment with one preferred agent. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. MDI formulation quantity limits: 2 inhalers / 30 days

	XOPENEX (levalbuterol) Inhaler	
Inhaled Beta2 Agonists (long acting)		
***Must meet eligibility criteria** **Solutions** **Inhalers** *SEREVENT DISKUS (salmeterol) inhaler	**PA Required** **Solutions** BROVANA (arformoterol) solution PERFOROMIST (formoterol) solution **Inhalers** ARCAPTA Neohaler (indacaterol) STRIVERDI Respimat (olodaterol)	**SEREVENT** ® will be approved for members with moderate to very severe COPD. Non-preferred agents will be approved for members with moderate to severe COPD, AND members must have failed a trial of **Serevent**®. (Failure is defined as lack of efficacy with a 6-week trial, allergy, intolerable side effects, or significant drug-drug interaction. **For treatment of members with diagnosis of asthma needing add-on therapy, please refer to preferred agents in combination Long-Acting Beta Agonist/Inhaled Corticosteroid. SEREVENT will not be approved for treatment of asthma in members needing add-on therapy due to safety risks associated with monotherapy.
Inhaled Corticosteroids		
No PA Required **Solutions** Budesonide nebules 0.25mg 0.5mg, 1mg **Inhalers** ASMANEX Twisthaler (mometasone) FLOVENT Diskus (fluticasone) FLOVENT HFA (fluticasone) PULMICORT Flexhaler (budesonide)	**PA Required** **Solutions** PULMICORT (budesonide) nebules 0.25mg 0.5mg, 1mg **Inhalers** ALVESCO (ciclesonide) inhaler ARNUITY Ellipta (fluticasone furoate) ASMANEX HFA (mometasone furoate) inhaler QVAR Redihaler (beclomethasone)	Non-preferred inhaled corticosteroids will be approved in members with asthma who have failed an adequate trial of two preferred agents. An adequate trial is defined as at least 6 weeks. (Failure is defined as: lack of efficacy with a 6-week trial, allergy, contraindication to, intolerable side effects, or significant drug-drug interactions.) Maximum Dose: Pulmicort (budesonide) nebulizer solution: 2mg/day
Inhaled Corticosteroid Combinations		
No PA Required ADVAIR Diskus BNR (fluticasone/salmeterol) ADVAIR HFA (fluticasone/salmeterol) DULERA (mometasone/ formoterol)	**PA Required** AIRDUO Respiclick (fluticasone/salmeterol) BREO Ellipta (vilanterol/fluticasone furoate) Budesonide/formoterol inhaler (generic Symbicort)	Non-preferred inhaled corticosteroid combinations will be approved for members meeting both of the following criteria: • Member has a qualifying diagnosis of asthma or severe COPD; AND • Member has failed two preferred agents (Failure is defined as lack of efficacy with a 6 week trial, allergy, intolerable side effects, significant drug-drug interactions, or dexterity/coordination limitations (per provider notes) that significantly impact appropriate use of a specific dosage form.) **Trelegy Ellipta®** prior authorization will be approved if the member has trialed/failed three preferred inhaled corticosteroid combination products AND Spiriva Handihaler®. Failure is defined as lack of efficacy with a 6-week trial, allergy, intolerable side effects, significant

SYMBICORT[BNR] (budesonide/formoterol) inhaler	Fluticasone/salmeterol (generic Airduo) Fluticasone/salmeterol Diskus (generic Advair) TRELEGY Ellipta (Fluticasone Furoate/Umeclidinium/Vilanterol) WIXELA Inhub (fluticasone/salmeterol)	drug-drug interactions, or dexterity/coordination limitations (per provider notes) that significantly impact appropriate use of a specific dosage form.