



Benefits Collaborative FAQs: Medical Necessity

This FAQ document summarizes:

Frequently asked questions regarding Department efforts to define the term Medical Necessity through the Benefits Collaborative Process; and

Suggestions made within the Benefits Collaborative Process – and supported by more than one stakeholder – for how to improve the draft Medical Necessity definition.

Below each item, the Department has provided an *interim* response.

Important Note: The development of a single Medical Necessity definition is ongoing; there are many stages of the Benefits Collaborative Process that the draft definition has *yet* to complete. This FAQ document is a snapshot of the Department position as of 7/6/2015 and should not be read as a final policy determination.

Item 1

Why is the Department creating a single, uniform definition of Medical Necessity for all programs, rules, and Department contracts?

Multiple definitions of the term Medical Necessity, containing similar but not identical language, exist within Colorado Medical Assistance Program rule and within various Department contracts

- Inconsistent language creates unnecessary confusion.
- Inconsistent language causes staff, clients, providers, and others needless investigative work.
- It is administratively burdensome to keep all definitions updated and consistent with one another.
- It is administratively burdensome to apply multiple standards for different contractors and providers.
- Creating a single, uniform definition is the right thing to do in terms of being transparent.

Item 2

Will the definition created be *applied* the same way across all Medicaid programs?

No, the creation of a single definition of Medical Necessity does not mean there is only one way to apply that definition.



- Example: The definition states that medically necessary services must be clinically appropriate in terms of amount, scope, and duration. However, what constitutes the clinically appropriate amount, scope, and duration of services for a particular benefit (such as transplants or private duty nursing) may be outlined in federal or state rules or state policies such as a Benefit Coverage Standard.

Item 3

What was the definition of Medical Necessity originally proposed by the Department at the start of the Benefits Collaborative process, on January 13, 2015?

Originally, the Department proposed that the following definition of Medical Necessity be included in 10 C.C.R. 2505-10, section 8.076.1.8. **Important Note:** Many stakeholder comments captured in this document are in response to the *original* proposed language immediately below; Department responses herein reflect *current* proposed language (see *Item 12* for *current proposed Medical Necessity definition*).

- *Medical necessity means a Medical Assistance program good or service that will, or is reasonably expected to prevent, diagnose, cure, correct, reduce, or ameliorate the pain and suffering, or the physical, mental, cognitive, or developmental effects of an illness, condition, injury, or disability. It may also include a course of treatment that includes mere observation or no treatment at all. A good or service is medically necessary only if:*
 - It is provided in accordance with generally accepted standards of medical practice in the United States; and*
 - It is clinically appropriate in terms of type, frequency, extent, site, and duration; and*
 - It is not primarily for the economic benefit of the provider or for the convenience of the client, caretaker, or provider; and*
 - There is no equally effective and less costly treatment option for the medical problem; and*
 - It is delivered in the most appropriate setting required by the client's condition; and*
 - It is not experimental or investigational.*

Item 4

How can I learn more about the Department's proposal?

To learn more about what the Department proposed at the start of the Medical Necessity Benefits Collaborative Process – and why, you may view the Power Point presentation dated January 13, 2015, located on the Benefits Collaborative Meeting Schedule webpage at <https://www.colorado.gov/pacific/sites/default/files/Benefits%20Collaborative%20Medical%20Necessity%20Presentation%20January%2013%2C%202015.pdf>



Item 5

Bullet C, in the Medical Necessity Definition proposed on January 13, 2015 (*see Item 3 above*), may need to be reworked.

What is meant by the word “primarily”? Who determines this? Can the word be changed to something less ambiguous?

- The word “primarily” means “for the most part; mainly” The term appears more than one hundred times in the Colorado Revised Statutes and, as such, the meaning is well established.
- Primary purpose is looked at by utilization review contractors for services or items subject to prior authorization or by compliance auditors or reviewers performing compliance monitoring. An adverse action as the result of a review is appealable.

Can this bullet be broken into two separate bullets: one for the “economic benefit” language and another for the “convenience” language?

The language proposed appears presently in section 8.076.1.8 of rule. The Department seeks to maintain the integrity of the current rule language as much as possible to avoid unintended changes to precedent and the operations of the program. We, therefore, propose keeping the bullet intact and adding the word ‘primarily’ before the word ‘convenience’ to create separation between the two concepts.

- The new language would read *“It is not primarily for the economic benefit of the provider or primarily for the convenience of the client, caretaker, or provider.”*

Can this bullet be further broken-out to separate “provider” from “client”?

The clause, as written immediately above, limits economic benefit considerations to the provider sufficiently.

Bullet C may be superfluous; if something is medically necessary, as indicated in the first paragraph of the proposed definition, does it matter if it is also convenient or of economic benefit? Can Bullet C be eliminated?

The client’s medical needs should be the determining factor of whether a service or item is medically necessary. The convenience of the provider, a caretaker or a client, or the economic benefit of the provider cannot be the determining factor regarding whether a service or item is needed, which service or item is needed, or the level of service or item which is needed. This language is designed to protect against inappropriate utilization and/or prescription.

- For example, the unique postural needs of many clients who use wheelchairs require that those clients receive highly individualized wheelchair seating configurations. This clause communicates that providers should not upsell clients on technology that they do not need – and that may not best meet the needs of their condition – but, rather, should ensure that the client’s medical needs are the chief determining factor in the technology prescribed.



Item 6

Bullet D, in the Medical Necessity Definition proposed on January 13, 2015 (*see Item 3 above*), may also need to be reworked.

What is meant by the term “medical problem?” Can the language be changed to read “There is no equally effective and less costly treatment option?”

- Presently, the term “for the client condition” appears in section 8.076.1.8. of rule; the Department proposed “for the medical problem” as alternative language after stakeholders expressed concern with the term “client condition.”
- The Department supports the recommendation made on January 13, to eliminate the need for either term, by ending the clause after the word “option.”
 - The new language would read *“There is no equally effective and less costly treatment option.”*

What is meant by the term “equally effective?” Who determines this? Can the language be changed to read “equally effective and individually appropriate?”

- The statement that services are deemed medically necessary when “there is no equally effective and less costly treatment option” indicates that, if there are two – or more – treatments that best meet the client’s needs (i.e. they are equally effective), the least costly treatment option shall be covered.
- “Equally effective” is looked at by utilization review contractors for services or items subject to prior authorization or by compliance auditors or reviewers performing compliance monitoring. An adverse action as the result of a review is appealable.
- “Equally effective” is the term used in the current medical necessity definition found in the EPSDT section of Colorado Medicaid Volume 8 rule at 10 C.C.R. 2505-10, section 8.280.1. The current medical necessity definition found in the Program Integrity section of rule (at 8.076.1.8.) stipulates that services are deemed medically necessary when “performed in a cost effective...setting.” The latter wording puts the emphasis on cost, the former puts the emphasis on care.
- By replacing the “cost effective” language in section 8.076.1.8 with “equally effective,” the Department is broadening the definition of medical necessity for non-EPSDT services.



Item 7

In Bullet E of the Medical Necessity Definition proposed on January 13, 2015 (*see Item 3 above*), can the “most appropriate setting” language be modified to align with language in CMS rules which states clients with disabilities may receive services in the most integrated setting (i.e. not just in a clinical office but also in the home and in the workplace)?

The Department understands the CMS regulations referenced to be specific to waiver services. The medical necessity definition must be broad enough to address both waiver services and State Plan Medicaid services.

Changing “setting” to “setting(s)” may accomplish the request above.

The Department supports the recommendation made on January 13, 2015 to change “setting” to setting(s).”

- The new language would read “It is delivered in the most appropriate setting(s) required by the client’s condition.”

Item 8

In one of the several definitions of Medical Necessity currently found in Medicaid rule, this one under the EPSDT section of rule at 10 C.C.R. 2505-10, section 8.280.1, language is included that pertains to Activities of Daily Living (ADLs) that cannot be found in the definition proposed by the Department in January; why?

The EPSDT Medical Necessity language referenced above states that a covered service shall be deemed a medical necessity if (among other factors) “the service will, or is reasonably expected to assist the individual to achieve or maintain maximum functional capacity in performing Activities of Daily Living.”

- The Department did not include the specific ADL language in the uniform definition proposed on January 13, 2015 (*see item 3 above*) because staff believed the intent of the language was already captured in the first paragraph of the proposed definition where it states, “Medical necessity means a Medical Assistance program, good, or service that will, or is reasonably expected to...reduce or ameliorate the...effects of a...condition...or disability.”
- Upon further examination, the Department agrees that there is a difference between something that is expected to reduce or ameliorate the effects of a condition or disability and something that is reasonably expected to assist an individual to achieve or maintain maximum functional capacity (*see below*).



Can the Department consider including the “maintain maximum functional capacity” language found within the ADL provision in the new definition?

This language appears to be specific to EPSDT. The Department proposes that the language *not* be included in the proposed, uniform Medical Necessity definition at 8.076.1.8 but, rather, it be *moved* within the EPSDT section of rule, from 8.280.1 to 8.280.4.E, and that it exist as an alternative to the criteria specified in the first paragraph of the proposed, uniform definition (*see example ADL language in item 13 below*).

Item 9

Also in 10 C.C.R. 2505-10, section 8.280.1, language currently reads that a service shall be deemed a medical necessity if (among other factors) it is reasonably expected to prevent or diagnose the onset of a “secondary disability.” Can mention of “secondary disability” be included in the new definition?

The proposed language is not limited to a primary disability; the inclusion of a reference to secondary is not needed.

Item 10

What *was* the definition of Medical Necessity proposed by the Department as of the last iteration of this FAQ document, on March 4, 2015?

On March 4, 2015, based on the input received on - and subsequent to - January 13, 2015, the Department proposed that the following definition of Medical Necessity be included in 10 C.C.R. 2505-10, section 8.076.1.8. **Important Note:** this definition has undergone further revision post March, 4, 2015 (*see item 12 below for current proposed Medical Necessity definition*).

- *Medical necessity means a Medical Assistance program good or service that will, or is reasonably expected to prevent, diagnose, cure, correct, reduce, or ameliorate the pain and suffering, or the physical, mental, cognitive, or developmental effects of an illness, condition, injury, or disability. It may also include a course of treatment that includes mere observation or no treatment at all. A good or service is medically necessary only if:*
 - a) *It is provided in accordance with generally accepted standards of medical practice in the United States; and*
 - b) *It is clinically appropriate in terms of type, frequency, extent, site, and duration; and*
 - c) *It is not primarily for the economic benefit of the provider or primarily for the convenience of the client, caretaker, or provider; and*
 - d) *There is no equally effective and less costly treatment option; and*
 - e) *It is delivered in the most appropriate setting(s) required by the client’s condition; and*
 - f) *It is not experimental or investigational.*



Item 11

On March 5, 2015, the Colorado Center for Law and Policy (CCLP) provided the Department with a response letter to the Medical Necessity Definition proposed on January 13, 2015 (*see Item 3 above*). The letter may be found, in-full, at the following link:

<https://www.colorado.gov/pacific/sites/default/files/Benefits%20Collaborative%20Medical%20Necessity%20CCLP%20Feedback%20January%202013%2C%202015.pdf>

The Department has carefully considered the feedback therein and responses to each item are provided below.

Issue: Implied restriction of covered goods and services

- The Department agrees that the first sentence of the medical necessity definition proposed on January 13, 2015 is ambiguous and proposes changing the language.
 - The new language would read "*Medical necessity means that a Medical Assistance program good or service will, or is reasonably expected to...*"
- The Department disagrees that the uniform definition found at 8.076.1.8 "should indicate that medical necessity under the pediatric benefit is subject to the parameters set out in EPSDT... and should...reference the language that now appears in 10 CCR 2505-10.8.280.1." Such a reference to EPSDT would be out-of-place in a section of rule meant to apply to all Medical Assistance programs.

Instead, the Department proposes that, *within* the EPSDT section of rule:

- (at 8.280.4.E) a reference to the 8.076.1.8 uniform medical necessity definition be included; and *also*
- (at 8.280.1) the current language describing federal policy be *retained* (*see example language in Item 13 below*).

Issue: Other definitional limitations that concern parameters set by EPSDT law and regulation

- The revisions proposed to the EPSDT section of rule (8.280) *do* make it clear that what is clinically appropriate for children "*may include greater frequency, extent and duration of services than is provided in the State Plan.*" This is accomplished by retaining the reference to federal regulation (1905(r)), in which such language can be found (*see example language in Item 13 below*).
- Additional language does not need to be added to either the 8.076.1.8 or 8.280 sections of rule to make it clear that "*flexibility in 'site' or 'type' of services is required when determining what is medically necessary for children.*" Nowhere in the proposed medical necessity definition (*see item 12 below*) does



the language limit care to a single site or type; the language only requires that the site or type be appropriate.

- As noted in Item 2 above, what is clinically appropriate for one population may not be clinically appropriate for another; the EPSDT section of rule clearly points to all federal regulations that detail what is clinically appropriate for children, and will continue to do so.
- The Department has made changes to Bullet C (*see item 5 above*).
- The Department agrees with the removal of the term "medical problem" in Bullet D (*see Item 6 above*).

Issue: Inconsistent terms

As indicated above, the Department agrees that the first sentence of the medical necessity definition proposed on January, 13, 2015 is ambiguous and has proposed a change.

Issue: Benefits of the existing EPSDT-specific definition

- The Department agrees that the citation to the medical necessity definition, within the EPSDT section of rule, should be introduced "*with a paragraph that define[s] EPSDT and cites relevant federal law and regulations... [making] it clear that certain federal laws and regulations apply,*" which is why the Department is proposing that *all* citations to federal EPSDT regulations *remain* in the EPSDT section of rule (at 8.280.1) and that a reference to the uniform medical necessity definition *follow* those citations in section 8.280.4.E. (*see Item 13 below*).
- The Department further suggests that the language in section 8.280.4.E include the following sentence:
 - "All medically necessary services described in section 1905(a) of the Social Security Act are a covered benefit under EPSDT, whether or not such services are covered under the State Plan." (See item 13 below.)
- As mentioned above (*see item 8*) The Department also proposes that the ADL provision that currently appears in section 8.280.1 of rule be *moved* within the EPSDT section of rule, from 8.280.1 to 8.280.4.E, and that it exist as an alternative to the criteria specified in the first paragraph of the proposed, uniform definition (*see Item 13 below*).

Item 12

What is the definition of Medical Necessity proposed by the Department as of now, July 6, 2015?

On March 4, 2015, the Department proposed a revised definition of Medical Necessity be included in 10 C.C.R. 2505-10, section 8.076.1.8. (*see Item 10 above*). After receiving further stakeholder feedback, including feedback from CCLP and our own Program Integrity Unit, the Department has made further formatting changes and proposes that the Medical Necessity definition read as follows. Note: items d-f have been re-ordered for ease of reading.



- *Medical necessity means that a Medical Assistance program good or service will, or is reasonably expected to, prevent, diagnose, cure, correct, reduce, or ameliorate the pain and suffering, or the physical, mental, cognitive, or developmental effects of an illness, condition, injury, or disability. It may also include a course of treatment that includes mere observation or no treatment at all. The good or service is medically necessary only if:*
 - a) *It is provided in accordance with generally accepted standards of medical practice in the United States; and*
 - b) *It is clinically appropriate in terms of type, frequency, extent, site, and duration; and*
 - c) *It is not primarily for the economic benefit of the provider or primarily for the convenience of the client, caretaker, or provider; and*
 - d) *It is delivered in the most appropriate setting(s) required by the client's condition; and*
 - e) *It is not experimental or investigational; and*
 - f) *There is no equally effective and less costly treatment option.*

Item 13

What is the change to the EPSDT section of rule (8.280) proposed by the Department as of now, July 6, 2015?

- As of July 6, 2015, The Department proposes that medical necessity language currently found in section 8.280.1 of rule be omitted and that new language be included in section 8.280.4.E; all other language within all sections of EPSDT rule (under 8.280) would remain the same.
- As of July 6, 2015, the Department proposes that the following language appear in 10 C.C.R. 2505-10, sections 8.280.1 and 8.280.4.E. (Note: new language is underlined, deleted language is ~~struck through~~).
- *8.280.1. Definitions*

Early and Periodic Screening, Diagnosis and Treatment (EPSDT) means the child health component of Medicaid. The EPSDT program requires coverage of periodic and interperiodic screens, vision, dental and hearing care, diagnostic services needed to confirm the existence of a physical or mental illness or condition, and all medical assistance services that are recognized under section 1905 of the Social Security Act, even if not offered under the state plan pursuant to federal laws applicable to the program (including 1905(a), 42 U.S.C. §§1396a(a)(42), 1396d(a)(4)(B) and 1396d(r)).

EPSDT Case Management means an activity that assists Medicaid clients in getting and/or coordinating services based on individual need.

EPSDT Outreach means methods to inform recipients or potential recipients, such as those found to be presumptively eligible, to enter into care.



EPSDT Outreach and Case Management Entity means an entity that has contracted with the Department to provide the activities specified in 8.280.3 below.

Medical Necessity means that a covered service shall be deemed a medical necessity or medically necessary if, in a manner consistent with accepted standards of medical practice, it:

1. Is found to be an equally effective treatment among other less conservative or more costly treatment options, and

2. Meets at least one of the following criteria:

a. The service will, or is reasonably expected to prevent or diagnose the onset of an illness, condition, primary disability, or secondary disability.

b. The service will, or is reasonably expected to cure, correct, reduce or ameliorate the physical, mental cognitive or developmental effects of an illness, injury or disability.

c. The service will, or is reasonably expected to reduce or ameliorate the pain or suffering caused by an illness, injury or disability.

d. The service will, or is reasonably expected to assist the individual to achieve or maintain maximum functional capacity in performing Activities of Daily Living.

Medical necessity may also be a course of treatment that includes mere observation or no treatment at all.

Personal Care Services means assistance with non-skilled activities of daily living in order to meet the client's physical, maintenance and supportive needs. This assistance may take the form of hands-on assistance (actually performing a task for the person), or prompting or cueing the client to complete the tasks.

➤ 8.280.4.E. Other EPSDT Benefits

Other health care services may include other EPSDT benefits if the need for such services is identified. The services are a benefit when they meet the following requirements:

- 1. The service is in accordance with generally accepted standards of medical practice.*
- 2. The service is clinically appropriate in terms of type, frequency, extent, and duration.*
- 3. The service provides a safe environment or situation for the child.*
- 4. The service is not for the convenience of the caregiver.*
- 5. The service is medically necessary.*



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~~6. The service is not experimental or investigational and is generally accepted by the medical community for the purpose stated.~~

~~7. The service is the least costly.~~

All medically necessary services described in section 1905(a) of the Social Security Act are a covered benefit under EPSDT, whether or not such services are covered under the State Plan. A service that will, or is reasonably expected to, assist the client to achieve or maintain maximum functional capacity in performing one or more Activities of Daily Living and meets the criteria for medical necessity set forth at 10 C.C.R. 2505-10 section 8.076.1.8.a-f is also medically necessary under EPSDT.