

Title of Rule: Revision to the Medical Assistance Health Programs Office Benefits and Operations Division Rule Concerning Women's Health Services, Section 8.731  
Rule Number: MSB 14-11-19-D  
Division / Contact / Phone: HPO B&O / Melanie Reece / x3693

**STATEMENT OF BASIS AND PURPOSE**

1. Summary of the basis and purpose for the rule or rule change. (State what the rule says or does and explain why the rule or rule change is necessary).

The Department is updating this rule to include content from the Women's Health Services Benefit Coverage Standard. Specifically, the rule will define the amount, scope and duration of the benefit.

2. An emergency rule-making is imperatively necessary

- to comply with state or federal law or federal regulation and/or  
 for the preservation of public health, safety and welfare.

Explain:

3. Federal authority for the Rule, if any:

§1905(a) of the Social Security Act, codified at 42 U.S.C. 1396d(a)(2); 42 CFR § 440.230.

4. State Authority for the Rule:

25.5-1-301 through 25.5-1-303, C.R.S. (2014);

Initial Review **04/10/2015**  
Proposed Effective Date **07/01/2015**

Final Adoption **05/08/2015**  
Emergency Adoption

**DOCUMENT #07**

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## **REGULATORY ANALYSIS**

1. Describe the classes of persons who will be affected by the proposed rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the proposed rule.

This rule will impact clients and providers of women's health services.

2. To the extent practicable, describe the probable quantitative and qualitative impact of the proposed rule, economic or otherwise, upon affected classes of persons.

Clearly defined and updated rules will improve client access to appropriate, high quality, cost-effective and evidence-based services while improving the health outcomes of Medicaid clients. Established criteria within rule will provide guidance to clients and providers regarding benefit coverage.

3. Discuss the probable costs to the Department and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues.

This rule does not have any costs to the Department or any other agency as a result of its implementation and enforcement.

4. Compare the probable costs and benefits of the proposed rule to the probable costs and benefits of inaction.

Clearly defined and updated rules increase client access to appropriate services and allow the Department to administer benefits in compliance with federal and state regulations, as well as clinical best practices and quality standards. Defining this benefit in rule will educate clients about their benefits and provide better guidance to service providers. The cost of inaction could result in decreased access to services, poor quality of care, and/or lack of compliance with state and federal guidance.

All of the above translates into appropriate cost-effective care administered by the state.

5. Determine whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.

There are no less costly methods or less intrusive methods for achieving the purpose of this rule. The department must appropriately define amount, scope and duration of this benefit in order to responsibly manage it.

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6. Describe any alternative methods for achieving the purpose for the proposed rule that were seriously considered by the Department and the reasons why they were rejected in favor of the proposed rule.

The Department also documents its benefit coverage policies in written coverage standards. The benefit coverage policies must be written into rule to have the force of rule.

1 **8.731 WOMEN'S HEALTH SERVICES**

2 **8.731.1 Definitions**

3 **BRCA** means a mutation in breast, ovarian, tubal, or peritoneal cancer susceptibility genes. The  
4 mutation may be either BRCA1 or BRCA2.

5 **BRCA Screening** means to assess whether a client has a documented biological family history  
6 of breast, ovarian, tubal, or peritoneal cancer that may be associated with an increased risk for  
7 potential mutation in breast cancer susceptibility genes (BRCA1 and BRCA2).

8 **Sterile/Sterility** means permanently rendered incapable of reproducing.

9 **8.731.2 Client Eligibility**

10 8.731.2.A. All female and transgender Medicaid clients are eligible for women's health  
11 services.

12 **8.731.3. Provider Eligibility**

13 8.731.3.A. All Colorado Medicaid enrolled providers are eligible to provide maternity  
14 services when it is within the scope of the provider's practice.

15 **8.731.4. Covered Services**

16 8.731.4.A. Women's Health Services are covered when medically necessary, as  
17 defined at Section 8.076.8, and within the limitations described in this  
18 section 8.731 and under 10 CCR 2505-10 as applicable.

19 8.731.4.B. All services are covered as often as clinically indicated, unless otherwise  
20 restricted under this rule.

21 8.731.4.C. The following services are covered:

22 1. Annual gynecological exam

23 2. Cervical cancer screening and follow-up

24 a. Cervical cancer screenings are only covered once per state fiscal year,  
25 unless clinical indication requires additional screening.

26 b. Further diagnostic and treatment procedures are covered as clinically  
27 indicated.

28 3. Sexually transmitted disease/infection testing, risk counseling, and treatment

29 4. Human Papillomavirus (HPV) vaccination

30 a. HPV vaccination is only covered for clients ages 9 through 26.

31 b. For clients ages 9 through 18 who are covered through the Vaccines for  
32 Children program, only the administration of the vaccine is covered in  
33 accordance with 8.200.3.C.2.

- 1 c. For clients ages 19 through 26, the administration of the vaccine and the  
2 vaccine are covered in accordance with 8.200.3.C.2.
- 3 5. BRCA screening, genetic counseling, and testing
- 4 a. BRCA screening, genetic counseling, and testing is only covered for  
5 clients over the age of 18.
- 6 b. BRCA screening is covered and must be conducted prior to any BRCA-  
7 related genetic testing.
- 8 c. The provider shall make genetic counseling available to clients with a  
9 positive screening both before and after genetic testing, if the provider is  
10 able, and genetic counseling is within the provider's scope of practice. If  
11 the provider is unable to provide genetic counseling, the provider shall  
12 refer the client to a genetic counselor.
- 13 d. Genetic testing for breast cancer susceptibility genes BRCA1 and  
14 BRCA2 is covered for clients with a positive screening.
- 15 6. Mammography
- 16 a. Mammography is covered for clients who are age 40 and older; or, have  
17 been clinically assessed as at high risk for, or have a history of, breast  
18 disease.
- 19 7. Mastectomy
- 20 a. Mastectomy is covered for women who have a positive genetic test as a  
21 BRCA mutation carrier.
- 22 b. Bilateral mastectomy is a covered benefit when there is a known breast  
23 disease in either breast.
- 24 c. Prophylactic bilateral mastectomy is a covered benefit for women who  
25 have tested positive for the BRCA1 or BRCA2 mutation or have a  
26 personal history of breast disease.
- 27 d. For clients who have undergone a mastectomy, a maximum of two  
28 mastectomy brassieres are covered per year.
- 29 8. Breast reconstruction is covered within five years of a mastectomy.
- 30 9. Breast reduction procedures are covered for clients with macromastia and there  
31 is a documented failure of alternative treatment for macromastia.
- 32 10. Hysterectomy
- 33 a. Hysterectomy is covered when performed solely for medical reasons and  
34 when all of the following conditions are met:
  - 35 i) The client is over the age of 20, or is a BRCA1 or BRCA2 carrier  
36 over the age of 18;

- 1                   ii)       The person who secures the authorization to perform the  
2                   hysterectomy has informed the client, or the client's authorized  
3                   representative, as defined in Section 8.057.1, orally and in  
4                   writing that the hysterectomy will render the client Sterile;
- 5                   iii)       The client, or the client's authorized representative, as defined in  
6                   Section 8.057.1, has acknowledged in writing, that the client or  
7                   representative has been informed the hysterectomy will render  
8                   the client Sterile; and
- 9                   iv)       The Department or its designee has been provided with a copy  
10                  of the written acknowledgment under 8.731.4.C.10.a.iii. The  
11                  acknowledgement must be received by the Department or its  
12                  designee before reimbursement for any services related to the  
13                  procedure will be made.
- 14                b.       A written acknowledgment of Sterility from the client is not required if  
15                either of the following circumstances exist:
- 16                    i)       The client is already Sterile at the time of the hysterectomy; or,
- 17                    ii)       The client requires a hysterectomy because of a life-threatening  
18                    emergency in which the physician determines prior  
19                    acknowledgement is not possible.
- 20                c.       If an acknowledgement of Sterility is not required because of the  
21                8.731.4.C.10.b exceptions, the physician who performs the hysterectomy  
22                shall certify in writing that either:
- 23                    i)       The client was already Sterile, stating the cause of that sterility;  
24                    or,
- 25                    ii)       The hysterectomy was performed under a life-threatening  
26                    emergency situation in which the physician determined prior  
27                    acknowledgement was not possible. The physician must include  
28                    a description of the emergency.
- 29                    iii)       The Department or its designee has been provided with a copy  
30                    of the physician's written certificate under 8.731.4.C.10.c. The  
31                    acknowledgement must be received by the Department or its  
32                    designee before reimbursement for any services related to the  
33                    procedure will be made.

#### 34   **8.731.5 Non-Covered Services**

- 35   8.731.5.A.     Prophylactic bilateral mastectomy is not covered when:
- 36                1.       There is no known breast disease present or personal history of breast disease,  
37                or,
- 38                2.       The client does not test positive for the BRCA1 or BRCA2 mutation.
- 39   8.731.5.B.     Hysterectomy for the sole purpose of sterilization.

- 1           1.       If more than one purpose for the hysterectomy exists, but the purpose of  
2           sterilization is primary, the hysterectomy is not a covered service.
- 3    8.731.5.C.     Routine BRCA genetic testing for clients whose family history is not associated  
4           with an increased risk of BRCA gene mutation is not covered.
- 5    **8.731.6. Prior Authorization**
- 6    8.731.6.A.     All breast reconstruction and reduction procedures require prior authorization.
- 7    8.731.6.B.     All BRCA genetic testing requires prior authorization.

DRAFT

**New Women's Health Services Rule (now includes Hysterectomies)***Rules have been structured to a standardized format***Women's Health Services (8.731)**

Hysterectomies were previously listed under Family Planning Services - now moved to "NEW" Women's Health Services Rule

<b>Original Numbering</b>	<b>New Numbering</b>	<b>Description</b>	<b>Change Status or Additions</b>
8.730.3	8.731.4.2.10	<b>Hysterectomies</b>	No Change is Rule, just moved so services are located in more appropriate section with women's health services. Hysterectomies are not part of family planning services.
8.730.3.A (1 & 2)	8.731.4.C.10.a (i, ii, iii)		No Change
8.730.3.B	8.731.4.C.10.a (iv)		No Change
8.730.3.C (1 & 2)	8.731.5.B & 8.731.5.B.1		No Change
8.730.3.D (1 & 2)	8.731.4.C.10.b (i, ii)		No Change
8.730.3.E (1 & 2)	8.731.4.C.10.c (i, ii)		No Change
8.730.3.F	8.731.4.C.10.d		