

Medical Necessity
Effective 09/01/2026

Plan	☒ MassHealth UPPL ☐ Commercial/Exchange	Program Type	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	Medical Benefit Pharmacy Benefit	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	N/A		

Overview

The purpose of this policy is to clarify the procedures used for reviewing prior authorization (PA) requests for the following drug therapies:

- drugs used for gender-affirming care
- drugs used for members less than 21 years of age due to medical necessity (EPSDT)

EPSDT (Early and Periodic Screening, Diagnostic, and Treatment) is a Medicaid program that ensures children under age 21 receive comprehensive preventive and treatment health services. It is a federally mandated component of Medicaid designed to provide children and adolescents under age 21 with comprehensive and preventive health care. (130 CMR 450.140-150)

Coverage Guidelines

Authorization of requested drug therapy may be approved when the following criteria have been met:

Gender-Affirming Care

1. There are no P&T-approved (Pharmacy & Therapeutic Committee) coverage guideline(s) for the requested drug and indication. If there are guideline(s) for the requested drug and indication, the request must be reviewed against the criteria listed on those guideline(s) first, as applicable
2. Documentation of a severe and persistent or widespread condition
3. Rationale or documentation of no other available treatment options (pharmacological or non-pharmacological) for **ONE** of the following:
 - a. An agent for the reduction of hair growth in a person with male sex assigned at birth/biologic male (transgender male to female)
 - b. **BOTH** of the following:
 - i. The provider attests the drug is necessary to the member's identity
 - ii. Documentation that the condition to be treated is negatively affecting the member's life as a transgender individual

Medical Necessity for ages <21 years old (EPSDT)

1. There are no P&T-approved (Pharmacy & Therapeutic Committee) coverage guideline(s) for the requested drug and indication. If there are guideline(s) for the requested drug and indication, the request must be reviewed against the criteria listed on those guideline(s) first, as applicable
2. Appropriate diagnosis
3. Member is less than 21 years of age
4. **ONE** of the following:
 - a. Medical records documenting an inadequate response, adverse reaction, or contraindication to **ALL** available appropriate formulary alternatives and/or drugs that are considered standard of care when available (required documentation of drug name, dose, duration of therapy, and reason for failure or discontinuation)
 - b. Member has condition for which there are no other formulary alternatives
 - c. For combination drugs, documentation of an inadequate response, adverse reaction, or contraindication to individual ingredients used together when available
 - d. Prescriber is requesting drug due to a drug shortage (must document drug shortage and anticipated duration of the shortage)

Continuation of Therapy

Reauthorization requires physician documentation of continuation of therapy and the following criteria:

1. Medical records or pharmacy history supporting that the member has been successfully maintained and compliant on current drug therapy
2. Member had a positive therapeutic response to current drug therapy
3. Documentation of clinical rationale, or provider attestation, that a change in therapy would result in instability of the member's medical condition

Limitations

1. Initial and reauthorization approvals will be granted for the following:
 - a. Gender affirming care: 12 months
 - b. EPSDT: up to 12 months or until member's 21st birthday, whichever is sooner

References

1. Commonwealth of MA MassHealth. (2025, November 7). *130 CMR 450.000* [Review of *130 CMR 450.000*]. <https://www.mass.gov/doc/proposed-regulation-date-filed-november-7-2025-0/download>
2. MassHealth Drug List. Accessed 8/28/26. MassHealth-Pharmacy-Operational-Page

Review History

9/13/23 – Created for P&T in response to the EPSDT requirement by MH where limitations and exclusions in 130 CMR 406.413(B) do not apply to medically necessary drug therapy for members under age 21. This was created to allow for consistent review for certain drugs. Effective 10/2/23

12/13/23 – Reviewed and updated for P&T. Policy was updated to reflect the change in regulation for coverage of cosmetic agents by adding “unless medically necessary”. Procedures for reviewing gender-affirming care agents specified. This regulation change will broaden the scope of review beyond EPSDT. Proposed criteria approved by MH on 12/28/23. Effective 1/2/24

04/10/24 – Reviewed and updated for P&T. Updated criteria for Cosmetic or Hair Growth Agents due to Medical Necessity. Removed verbiage regarding medical necessity for non-gender-affirming care requests. Updated initial approval duration to 12 months. Effective 05/06/24

11/12/25 - Reviewed and updated for P&T. Updated criteria following the B&L update. Included drugs that require additional EPSDT review. Effective 10/15/25



3/11/26 – Reviewed and updated for P&T. Bausch and Lomb added Cabtreo to be available on the patient assistance program (PAP). EPDST (<21) review still applies for drugs that have PA with PAP available. Effective 4/1/26

6/10/26 – Reviewed and updated for P&T. Formatting updated. Updated approval durations to reflect 21st birthday. Effective 7/1/26

9/9/26 - Reviewed and updated for P&T. Removed criteria for Bausch & Lomb products that were reviewed for under ages 21 due to regulatory requirements. Effective 9/1/26

