Mass General Brigham
Health Plan

Medical Necessity
Effective 05/06/2024

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 and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | 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)

Per MassHealth regulations:

406.413: Limitations on Coverage of Drugs

(B) Drug Exclusions. The MassHealth agency does not pay for the following types of prescription or over-the-counter drugs or drug therapy.

1. Cosmetic. The MassHealth agency does not pay for any drug when used for cosmetic purposes or for hair growth, unless medically necessary.
2. Cough and Cold. The MassHealth agency does not pay for any drug used solely for the symptomatic relief of coughs and colds, including but not limited to, those that contain an antitussive or expectorant as a major ingredient, unless dispensed to a member who is a resident in a nursing facility or an intermediate care facility for the mentally retarded (ICF/MR).
3. Fertility. The MassHealth agency does not pay for any drug used to promote fertility.
4. Less-than-effective Drugs. The MassHealth agency does not pay for any drug products (including identical, similar, or related drug products) that the U.S. Food and Drug Administration has proposed, in a Notice of Opportunity for Hearing (NOOH), to withdraw from the market because they lack substantial evidence of effectiveness for all labeled indications.
5. Experimental and Investigational Drugs. The MassHealth agency does not pay for any drug that is experimental, medically unproven, or investigational in nature.
6. Drugs for Sexual Dysfunction. The MassHealth agency does not pay for any drug when used for the treatment of sexual dysfunction.

Coverage Guidelines

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

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. **ONE** of the following:
    a. Requests for gender-affirming care drugs must meet **ALL** of the following:
        i. Documentation of a severe and persistent or widespread condition
        ii. Rationale or documentation of no other available treatment options (pharmacological or non-pharmacological) for **ONE** of the following:
            1. An agent for the reduction of hair growth in a person with male sex assigned at birth/biologic male (transgender male to female)
            2. **BOTH** of the following:
                a. The provider attests the drug is necessary to the member's identity
                b. Documentation that the condition to be treated is negatively affecting the member's life as a transgender individual
    b. Requests for all other drugs due to medical necessity (EPSDT) must meet **ALL** of the following:
        i. Member is less than 21 years of age
        ii. **ONE** of the following:
            1. 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)
            2. Member has condition for which there are no other formulary alternatives
            3. For combination drugs, documentation of an inadequate response, adverse reaction, or contraindication to individual ingredients used together when available
            4. 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 approvals will be granted for 12 months.
2. Reauthorizations will be granted for 12 months.

References

N/A

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