MEDICAL MUTUAL®

Drug Policy

Policy:	Imvexxy (estradiol vaginal insert)	Annual Review Date: 05/18/2023 Last Revised Date: 05/18/2023

OVERVIEW

Imvexxy is an estradiol vaginal insert indicated for the treatment of moderate to severe dyspareunia (painful sexual intercourse) resulting from vulvar and vaginal atrophy, a symptom of menopause.

POLICY STATEMENT

This policy involves the use of Imvexxy. Prior authorization is recommended for pharmacy benefit coverage of Imvexxy. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below. The following policy is for commercial plans using the Basic/Basic Plus or the National Preferred/National Preferred Plus formularies.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Imvexxy is recommended in those who meet the following criteria:

1. **Moderate to Severe Dyspareunia**
   Criteria. *Patient must meet the following criteria*
   - **A.** Patient is a post-menopausal woman with vulvar and/or vaginal atrophy; AND
   - **B.** Patient has had an inadequate response to at least one low-dose vaginal estrogen preparation (e.g. generic estrogen vaginal cream, generic estrogen vaginal insert, Yuvafem, Premarin vaginal cream, Estrace vaginal cream, Estring, Vagifem); AND
   - **C.** Patient does not have any contraindications to use of estrogens (e.g. history of breast cancer, estrogen-dependent neoplasia, undiagnosed abnormal genital bleeding, liver disease/impairment, history of or active DVT, PE, stroke, or MI); AND
   - **D.** Imvexxy will not be used in combination with other estrogen preparations or Osphena

2. **Patient has been started on Imvexxy**
   Criteria. *Patient must meet the following criteria*

A. The patient meets all the above criteria for new starts; AND
B. The patient has had an improvement on Imvexxy per the prescribing physician

Initial Approval/ Extended Approval.
A) *Initial Approval:* 2 months
B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Imvexxy has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Imvexxy [prescribing information]. Novato, CA: BioMarin Pharmaceutical Inc. November 2021.
2. Estradiol. In: DRUGDEX (online database). Truven Health Analytics: Greenwood Village, CO. Last updated 28 April 2023. Accessed on 16 May 2023.
3. Estradiol. In: Lexi-Drugs. Lexicomp. Wolters Kluwer Clinical Drug Information, Inc.; Riverwoods, IL. Available at: http://www.online.lexi.com. Last updated 11 May 2023. Accessed on 16 May 2023.