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| Effective Date: 12/01/2020 |
| Reviewed: 9/2020, 4/2021, 2/2022, 3/2023, 3/2024, 3/2025 |
| Scope: Medicaid |

OriaHnn (elagolix, estradiol and norethindrone) Myfembree (relugolix, estradiol and norethindrone)

POLICY

I. CRITERIA FOR APPROVAL

An authorization of 6 months may be granted when all the following criteria are met:

- A. Member is 18 years of age and older, **AND**
- B. Prescribed by or in consultation with a obstetrics/gynecologist (OB/GYN) or reproductive endocrinologist, **AND**
- C. Member has no history of osteoporosis or a bone mineral density T score of -1.5 or less at the lumbar spine, total hip or femoral neck, **AND**
- D. Member has not received more than 24 months of therapy with OriaHnn or Myfembree; **AND**

Uterine Fibroids

- E. The member has a documented diagnosis of heavy menstrual bleeding associated with uterine fibroids, **AND**
- F. Documentation that member is premenopausal, **AND**
- G. Documentation that the member has tried and failed OR had an intolerance or contraindication to at least three formulary alternatives (i.e., tranexamic acid, norethindrone, NuvaRing, etc.), **AND**
- H. Member has no history of pelvic inflammatory disease and/or persistent or complex ovarian cysts if they are requesting OriaHnn; **OR**

Pain Associated with Endometriosis

- I. Member has diagnosis of moderate to severe pain associated with endometriosis
- J. Documentation that member is premenopausal, **AND**
- K. Member has tried and failed OR had an intolerance, or contraindication after a three month trial of two analgesics (e.g., ibuprofen, meloxicam, naproxen); **AND**
- L. Member has tried and failed OR had an intolerance, or contraindication after a three month trial to one of the following: hormonal contraceptives or Progestins(e.g., norethindrone)
- M. If the member has been previously received treatment with an elagolix-containing product (e.g., OriaHnn, Orlissa) or a relugolix-containing product (e.g. Myfembree) the member has not already received ANY of the following: greater than 24 cumulative months of treatment with elagolix-containing products (e.g., OriaHnn, Orlissa) and/or relugolix-containing products (e.g. Myfembree), greater than six months of treatment with Orlissa 200 milligrams twice a day

II. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for all members who meet all initial criteria and who have documentation of a positive clinical response after at least 6 months of therapy with OriaHnn or

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Myfembree as evidenced by a decrease in heavy menstrual bleeding and/or pain associated with endometriosis and improvement in overall signs and symptoms of the condition.

III. QUANTITY LIMIT

- OriaHnn: 56 tablets per 28 days
- Myfembree: 28 tablets per 28 days

IV. COVERAGE DURATION

- Maximum of 24 months of therapy

V. REFERENCES

1. OriaHnn [package insert]. North Chicago, IL: AbbVie Inc.; June 2023.
2. MyFembree [package insert]. Brisbane, CA: Myovant Sciences, Inc.; July 2024.