

STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

ELAGOLIX/ESTRADIOL/NORETHINDRONE

| Generic | Brand | HICL | GCN | Medi-Span | Exception/Other |
|---------------|---------|-------|-----|--------------|-----------------|
| ELAGOLIX AND | ORIAHNN | 46577 | | GPI-10 | |
| ESTRADIOL AND | | | | (2499350340) | |
| NORETHINDRONE | | | | , | |

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Has the patient received a total of 24 months cumulative treatment with Oriahnn?

If yes, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

If no, continue to #2.

- 2. Is the request for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) and the patient meets **ALL** of following criteria?
 - The patient is 18 years of age or older
 - The patient is a premenopausal woman
 - Therapy is prescribed by or given in consultation with an OB/GYN

If yes, approve for 6 months by HICL or GPI-10 with a quantity limit of #2 per day.

APPROVAL TEXT: Renewal for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) requires the patient had improvement of heavy menstrual bleeding.

If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ELAGOLIX/ESTRADIOL/NORETHINDRONE** (**Oriahnn**) requires the following rule(s) be met for approval:

- A. The request is for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids: non-cancerous growths in the uterus)
- B. You are 18 years of age or older
- C. You are a premenopausal woman
- D. Therapy is prescribed by or given in consultation with an obstetrician or gynecologist (OB/GYN: doctor who specializes in women's reproductive system)
- E. You have not received a total of 24 months cumulative treatment with Oriahnn (*Initial denial text continued on next page*)

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ELAGOLIX/ESTRADIOL/NORETHINDRONE

INTIAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Has the patient received a total of 24 months cumulative treatment with Oriahnn?

If yes, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

If no, continue to #2.

- 2. Is the request for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) **AND** the patient meets the following criterion?
 - The patient has had improvement of heavy menstrual bleeding

If yes, approve for 18 months (or up to 24 months cumulative lifetime treatment duration) by HICL or GPI-10 with a quantity limit of #2 per day.

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ELAGOLIX/ESTRADIOL/NORETHISTERONE** (**Oriahnn**) requires the following rule(s) be met for renewal:

- A. The request is for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids: non-cancerous growths in the uterus)
- B. You had improvement of heavy menstrual bleeding on therapy
- C. You have not received a total of 24 months cumulative treatment with Oriahnn

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Oriahnn.

REFERENCES

• Oriahnn [Prescribing Information]. North Chicago, IL: AbbVie Inc., May 2020.

| Library | Commercial | NSA |
|---------|------------|-----|
| Yes | Yes | No |

Part D Effective: N/A Created: 08/20

Commercial Effective: 01/01/21 Client Approval: 11/20 P&T Approval: 07/20

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