STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RELUGOLIX-ESTRADIOL-NORETHINDRONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RELUGOLIX/ ESTRADIOL/ NORETHINDRONE ACETATE	MYFEMBREE	47392		GPI-10 (2499350380)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

   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** the following criteria?
   - The patient is 18 years of age or older
   - The patient is a premenopausal woman
   - Therapy is prescribed by or in consultation with an obstetrician or gynecologist (OB/GYN)

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #3.

3. Is the request for the management of moderate to severe pain associated with endometriosis and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is a premenopausal woman
   - Therapy is prescribed by or in consultation with an obstetrician or gynecologist (OB/GYN)
   - The patient's diagnosis is confirmed via surgical or direct visualization (e.g., pelvic ultrasound) or histopathological confirmation (e.g., laparoscopy or laparotomy) in the last 10 years
   - Myfembree will NOT be used concurrently with another GnRH-modulating agent (e.g., Orilissa, Lupron Depot, Synarel)

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 per day**.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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RELUGOLIX-ESTRADIOL-NORETHINDRONE

INITIAL CRITERIA (CONTINUED)

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 **RELUGOLIX-ESTRADIOL-NORETHINDRONE (Myfembree)** requires the following rule(s) be met for approval:

A. The request is for ONE of the following:
   1. Management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids: non-cancerous growths in the uterus)
   2. Management of moderate to severe pain associated with endometriosis (condition affecting the uterus)

B. **If the request is for management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids), approval also requires:**
   1. You are 18 years of age or older
   2. You are a premenopausal (before menopause) woman
   3. Therapy is prescribed by or in consultation with an obstetrician or gynecologist (OB/GYN: a type of women's health doctor)
   4. You have not received a total of 24 months cumulative (total) treatment with Myfembree

C. **If the request is for management of moderate to severe pain associated with endometriosis, approval also requires:**
   1. You are 18 years of age or older
   2. You are a premenopausal (before menopause) woman
   3. Therapy is prescribed by or in consultation with an obstetrician or gynecologist (OB/GYN: a type of women's health doctor)
   4. Your diagnosis of endometriosis is confirmed via surgical or direct visualization (such as pelvic ultrasound [type of imaging]) or histopathological (tissue) confirmation (such as laparoscopy [type of surgery] or laparotomy [type of surgery]) in the last 10 years
   5. Myfembree will NOT be used concurrently (at the same time) with another GnRH-modulating agent (such as Orilissa, Lupron Depot, Synarel)
   6. You have not received a total of 24 months cumulative (total) treatment with Myfembree

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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RELUGOLIX-ESTRADIOL-NORETHINDRONE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

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

   If yes, do not approve.
   DENIAL TEXT: See the renewal 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 #1 per day.**

   If no, continue to #3.

3. Is the request for the management of moderate to severe pain associated with endometriosis and the patient meets **ALL** of the following criteria?
   - The patient has had improvement in pain related to endometriosis
   - Myfembree will NOT be used concurrently with another GnRH-modulating agent (e.g., Orilissa, Lupron Depot, Synarel)

   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 #1 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 **RELUGOLIX-ESTRADIOL-NORETHINDRONE (Myfembree)** requires the following rule(s) be met for renewal:
   A. The request is for ONE of the following:
      1. Management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids: non-cancerous growths in the uterus)
      2. Management of moderate to severe pain associated with endometriosis (condition affecting the uterus)

   (Renewal denial text continued on next page)

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RELUGOLIX-ESTRADIOL-NORETHINDRONE

RENEWAL CRITERIA (CONTINUED)

B. **If the request is for management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids), renewal also requires:**
   1. You had improvement of heavy menstrual bleeding on therapy
   2. You have not received a total of 24 months cumulative (total) treatment with Myfembree

C. **If the request is for management of moderate to severe pain associated with endometriosis, renewal also requires:**
   1. You have had improvement in pain related to endometriosis while on therapy
   2. Myfembree will NOT be used concurrently (at the same time) with another GnRH-modulating agent (such as Orilissa, Lupron Depot, Synarel)
   3. You have not received a total of 24 months cumulative (total) treatment with Myfembree

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.

RATIONALE

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

REFERENCES

- Myfembree [Prescribing Information]. Brisbane, CA: Myovant Sciences, Inc., August 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 09/12/22
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P&T Approval: 04/22