Member Name: _____ Member ID: _____ Member DOB: _____

Drug Name: _____ Strength: _____ Directions (including frequency):_____

Physician Name: _____ Physician Phone #: _____ Specialty: _____

Physician Fax #: _____ Pharmacy Name: _____Pharmacy Phone: _____

Horizon NJ Health

Gonadotropin Releasing Hormones agonists and antagonists – Medical Necessity Request

Complete pages 1-4 for New/Initial Requests

Contraindication Information: Please choose the requested drug below and indicate if the member has any listed contraindications.

□ Leuprolide (Lupron)	□ Members who are breast-feeding □ Pregnant members or members who intend to become pregnant while on therapy □ NONE
□ Leuprolide (Lupron Depot)	□ Members who are breast-feeding □ Pregnant members or members who intend to become pregnant while on therapy □ Undiagnosed abnormal vaginal bleeding □ NONE
□ Leuprolide/norethindrone (Lupaneta Pack)	□ Members who are breast-feeding □ Pregnant members or members who intend to become pregnant while on therapy □ NONE
□ Leuprolide (Eligard, Fensolvi)	□ Pregnant members or members who intend to become pregnant while on therapy □ NONE
□ Degarelix (Firmagon)	□ Pregnant members or members who intend to become pregnant while on therapy □ NONE
□ Goserelin (Zoladex)	□ Pregnant members or members who intend to become pregnant while on therapy □ Members who are breast-feeding □ NONE
□ Histrelin (Vantas, Supprelin LA)	□ Pregnant members or members who intend to become pregnant while on therapy □ NONE
□ Nafarelin (Synarel)	□ Pregnant members or members who intend to become pregnant while on therapy □ Undiagnosed abnormal vaginal bleeding □ Members who are breast-feeding □ NONE
□ Triptorelin (Trelstar, Triptodur)	□ Pregnant members or members who intend to become pregnant while on therapy □ NONE
□ Elagolix (Orilissa)	□ Pregnant members or members who intend to become pregnant while on therapy □ Osteoporosis □ Severe Hepatic Impairment □ Concomitant use of strong anion transporting polypeptide (OATP) 1B1 inhibitors (e.g., cyclosporine and gemfibrozil) □ NONE
□ Elagolix, estradiol, and noresthindrone acetate and Elagolix (Oriahnn)	□ Pregnant members or members who intend to become pregnant while on therapy □ Undiagnosed abnormal vaginal bleeding □ Osteoporosis □ Severe Hepatic Impairment □ Concomitant use of strong anion transporting polypeptide (OATP) 1B1 inhibitors (e.g., cyclosporine and gemfibrozil) □ High risk of arterial, venous thrombotic, or thromboembolic disorder □ Current or history of breast cancer or other hormonally-sensitive malignancies, and with increased risk for hormonally-sensitive malignancies □ NONE
□ Leuprolide 65 mg implant (Viadur)	□ Pregnant members or members who intend to become pregnant while on therapy □ Pediatric patient □ NONE

Physician office's signature*_____ Print Name_____
***Form must be completed and signed by physician or licensed representative from the physician's office**.

Member Name: _____ Member ID: _____ Member DOB: _____

Drug Name: _____ Strength: _____ Directions (including frequency):_____

Physician Name: _____ Physician Phone #: _____ Specialty: _____

Physician Fax #: _____ Pharmacy Name: _____Pharmacy Phone: _____

Diagnosis Information: Please select diagnosis and answer related questions.

□ **Prostate Cancer**

a) Does the member have clinically localized disease (N0M0) and requesting neoadjuvant, concurrent, and/or adjuvant GnRH agonist/antagonist together with EBRT? **Yes or No**
   a. If yes, please indicate which of the following applies:
      □ Intermediate-risk disease requesting short-term (4-6 months) GnRH agonist/antagonist
      □ High-risk or very-high-risk disease
      □ Recurrent disease
      □ Locally advanced disease and PSA recurrence after radical prostatectomy without evidence of metastases
      □ None of the above

b) Does the member have regional disease which includes positive lymph nodes close to prostate and/or positive pelvic nodes? **Yes or No**
   a. If yes, please indicate which of the following applies:
      □ Requesting GnRH agonist/antagonist as primary treatment and life expectancy >5years
      □ Requesting GnRH agonist/antagonist together with EBRT
      □ Requesting neoadjuvant, concurrent, and/or adjuvant GnRH agonist/antagonist with EBRT and life expectancy >5 years
      □ Requesting GnRH agonist/antagonist after radical prostatectomy
      □ None of the above

c) Is the requested GnRH agonist/antagonist for palliative therapy? **Yes or No**
   a. If Yes, please indicate which of the following applies:
      □ Life expectancy ≤5 years with high-risk, very-high risk, regional, or metastatic disease
      □ Disease progressed (i.e. symptom development or changes in PSA suggestive of imminent symptoms) during observation
      □ None of the above

d) Is the request for metastatic disease? **Yes or No**

e) For Zoladex requests, will the member receive concomitant flutamide therapy? **Yes or No**

f) Please provide any additional information about the member's disease state:
   _____
   _____

□ **Uterine Fibroids (Leiomyomata)**

a) Does the member have anemia due to the fibroids? **Yes or No**
b) Will the member be undergoing surgery for the fibroids? **Yes or No**
c) Has the member tried iron therapy and if so, for how long? _____
d) Did the member respond to iron therapy? **Yes or No**
   a. If no, please let us know the specific reason for failure**:** _____
      _____
e) Will the member be receiving iron with the Lupron? **Yes or No**
   a. If no, please let us know why not? _____

Physician office's signature*_____ Print Name_____
***Form must be completed and signed by physician or licensed representative from the physician's office**.

Member Name: _____ Member ID: _____ Member DOB: _____

Drug Name: _____ Strength: _____ Directions (including frequency):_____

Physician Name: _____ Physician Phone #: _____ Specialty: _____

Physician Fax #: _____ Pharmacy Name: _____Pharmacy Phone: _____

□ **Precocious Puberty**

a) Is the precocious puberty either true or central? **Yes or No**
b) Has tumor been ruled out by appropriate diagnostic procedure? **Yes or No**
c) Does the member have an onset of secondary sexual characteristics that occurred at or before age 9? **Yes or No**

d) Does the member **only** have pubic hair and/or axillary hair and/or axillary odor as the only signs of sexual development? **Yes or No**

i. If Yes, does the member have one of the following (please indicate which):
- □ Diagnosis of Premature Adrenarche has been excluded
- □ Had a pubertal response to a GnRH stimulation test
- □ Bone age advanced one year beyond the chronological age
- □ Diagnosis has been confirmed by an endocrinologist
- □ None of the above

□ **Ovarian Cancer**

a) Please indicate which applies: Is the member: □ Pre-operative □ Post-operative
b) Does the member have any of the following (please indicate all that apply):
- □ Grade 1 endometrioid epithelial carcinoma or Low-grade serous carcinoma
  - a) Does the member have Stage IC, Stage II-IV disease? Yes or No
- □ Borderline epithelial tumors with invasive implants
- □ Recurrence of epithelial ovarian/fallopian tube/primary peritoneal disease
  - a) Has the member failed or is intolerant to preferred platinum based therapy or cytotoxic therapy or targeted single therapy? Yes or No
- □ Recurrence of malignant sex cord-stromal tumor, specifically granulosa cell tumor
- □ None of the above

d) Which therapies has the member previously failed, not tolerated, or has a contraindication to?

_____

_____ _____

□ **Ovarian Protection during Chemotherapy**

a) Will the medication be administered while receiving chemotherapy treatment? **Yes or No**
b) Is the member premenopausal? **Yes or No**

□ **Breast Cancer**

a) Is it recurrent? **Yes or No**
b) Is it metastatic? **Yes or No**
c) What is the member's menopausal status? □ Premenopausal □ Perimenopausal □ Postmenopausal
d) Does the member have hormone receptor positive breast cancer? **Yes or No**
e) What therapies will this medication be given in combination with? _____

_____

□ **Dysfunctional (Abnormal) Uterine Bleeding**

a) Will the member be undergoing surgery (endometrial ablation)? **Yes or No**
b) What is the abnormal bleeding associated with? (If it is due to one of the listed diagnoses, please also choose that diagnosis and answer related questions). _____
c) How many depot injections will the member receive before surgery (endometrial ablation)? _____
d) Once depot injections are given, after how many weeks will surgery be performed ? _____

Physician office's signature*_____ Print Name_____
***Form must be completed and signed by physician or licensed representative from the physician's office**.

Member Name: _____ Member ID: _____ Member DOB: _____

Drug Name: _____ Strength: _____ Directions (including frequency):_____

Physician Name: _____ Physician Phone #: _____ Specialty: _____

Physician Fax #: _____ Pharmacy Name: _____Pharmacy Phone: _____

□ **Menorrhagia (Heavy bleeding)/ Excessive or frequent menstruation**

a) How many total weeks of therapy has the member previously received of the requested drug? _____

b) What is the heavy bleeding associated with? (If it is due to one of the listed diagnoses, please also choose that diagnosis and answer related questions).
_____

c) What is the member's menopausal status? □ Premenopausal □ Perimenopausal □ Postmenopausal

d) Will the member be taking any other drugs for this diagnosis? **Yes or No** If yes, please list the specific drug:
_____

□ **Suppression of Menstruation or Ovarian Protection during Transplant**

a) Will the member be undergoing Bone Marrow Transplant? **Yes or No**

b) Is the member premenopausal? **Yes or No**

□ **Endometriosis**

a) How many total weeks of therapy has the member previously received of the requested drug? _____

b) For Orilissa requests:
   a) Can the member try any of the following drug(s) instead?: Lupron 3.75mg/Lupron Depot 11.25mg, Synarel Nasal Spray, Zoladex 3.6mg, Depo-SubQ Provera 104? **Yes** or **No**
   b) If **Yes**, please let us know which drug can be tried and let us know many total weeks of therapy the member has previously received: _____
   c) If **No**, please let us know the reason(s) why [note, if the member has already tried other drugs, please let us know which drugs were tried and the reason each was stopped]: _____
   d) Does the member have pain? **Yes** or **No**
      - If **Yes,** what is the severity of the pain? □ Mild □ Moderate □ Severe
   e) Does the member have Dyspareunia? **Yes** or **No**
   f) Does the member have moderate hepatic impairment (Child-Pugh Class B)? **Yes** or **No**

c) Will the member be taking any other drugs for this diagnosis? **Yes or No** If yes, please list the specific drug:
_____

□ **Gender Identity Disorder/Gender Incongruence or Gender Dysphoria**

For Adolescent members:

a) Does the member have mental health disorders? **Yes or No**
   - If **Yes,** are the mental health disorders reasonably well controlled? **Yes or No**

b) Has the member undergone surgery for gender reassignment (e.g. gonadectomy)? **Yes or No**

c) Has the member experienced puberty to at least Tanner stage 2? **Yes or No**

d) Has the member had (early) pubertal changes that have resulted in an increase of their gender dysphoria? **Yes or No**

e) Will the member be social support during treatment? **Yes or No**

f) Does the member demonstrate knowledge and understanding of the expected outcomes of GnRH analog treatment? **Yes or No**

For Adult members:

a) Does the member have mental health disorders? **Yes or No**
   - If **Yes,** are the mental health disorders reasonably well controlled? **Yes or No**

b) Has the member undergone surgery for gender reassignment (e.g. gonadectomy)? **Yes or No**

c) Does the member have the ability to make a fully informed decision and to consent for treatment? **Yes or No**

□ **Other**: _____

Physician office's signature*_____ Print Name_____

***Form must be completed and signed by physician or licensed representative from the physician's office**.

Member Name: _____ Member ID: _____ Member DOB: _____

Drug Name: _____ Strength: _____ Directions (including frequency):_____

Physician Name: _____ Physician Phone #: _____ Specialty: _____

Physician Fax #: _____ Pharmacy Name: _____Pharmacy Phone: _____

****Complete pages 5-6 ONLY for subsequent/renewal requests****

Diagnosis Information (please indicate diagnosis and answer related questions):

□ **Prostate Cancer**

a) Does the member have clinically localized disease (N0M0) and requesting neoadjuvant, concurrent, and/or adjuvant GnRH agonist/antagonist together with EBRT? **Yes or No**
   a. If yes, please indicate which of the following applies:
      □ Intermediate-risk disease requesting short-term (4-6 months) GnRH agonist/antagonist
      □ High-risk or very-high-risk disease
      □ Recurrent disease
      □ Locally advanced disease and PSA recurrence after radical prostatectomy without evidence of metastases
      □ None of the above

b) Does the member have regional disease which includes positive lymph nodes close to prostate and/or positive pelvic nodes? **Yes or No**
   a. If yes, please indicate which of the following applies:
      □ Requesting GnRH agonist/antagonist as primary treatment and life expectancy >5years
      □ Requesting GnRH agonist/antagonist together with EBRT
      □ Requesting neoadjuvant, concurrent, and/or adjuvant GnRH agonist/antagonist with EBRT and life expectancy >5 years
      □ Requesting GnRH agonist/antagonist after radical prostatectomy
      □ None of the above

c) Is the requested GnRH agonist/antagonist for palliative therapy? **Yes or No**
   a. If Yes, please indicate which of the following applies:
      □ Life expectancy ≤5 years with high-risk, very-high risk, regional, or metastatic disease
      □ Disease progressed (i.e. symptom development or changes in PSA suggestive of imminent symptoms) during observation
      □ None of the above

d) Is the request for metastatic disease? **Yes or No**

e) For Zoladex requests, will the member receive concomitant flutamide therapy? **Yes or No**

f) Is there any other information the physician's office can share about the member's disease state?
   _____

□ **Endometriosis**

a) Have symptoms recurred after 6 months of therapy? **Yes or No**

b) Will the member be concomitantly receiving Norethindrone? **Yes or No**

c) How many total weeks of therapy has the member previously received of the requested drug?
   _____

d) Does the member have pain? **Yes** or **No**
   - If **Yes,** what is the severity of the pain? □ Mild □ Moderate □ Severe

e) Does the member have Dyspareunia? **Yes** or **No**

f) Does the member have moderate hepatic impairment (Child-Pugh Class B)? **Yes** or **No**

g) Will the member be taking any other drugs for this diagnosis? **Yes or No** If yes, please list the specific drug:
   _____

□ **Uterine Fibroids (Leiomyomata)**

a) Has the member undergone Endometrial Ablation? **Yes or No**

Physician office's signature*_____ Print Name_____

***Form must be completed and signed by physician or licensed representative from the physician's office**.

Member Name: _____ Member ID: _____ Member DOB: _____

Drug Name: _____ Strength: _____ Directions (including frequency):_____

Physician Name: _____ Physician Phone #: _____ Specialty: _____

Physician Fax #: _____ Pharmacy Name: _____Pharmacy Phone: _____

□ **Precocious Puberty**

□ **Ovarian Cancer**

□ **Ovarian Protection during Chemotherapy**

a) Will the member be receiving chemotherapy treatment? **Yes or No**
b) Is the member premenopausal? **Yes or No**

□ **Breast Cancer**

a) Is the breast cancer recurrent? **Yes or No**
b) Is the breast cancer metastatic? **Yes or No**
c) What is the member's menopausal status? □ Premenopausal □ Postmenopausal □ Perimenopausal
d) Does the member have hormone receptor positive breast cancer? **Yes or No**
e) What therapies will this medication be given in combination with? _____
_____

□ **Dysfunctional (Abnormal) Uterine Bleeding**

a) Has the member undergone Endometrial Ablation? **Yes or No**

□ **Suppression of Menstruation or Ovarian Protection after Transplant**

a) Is the member post-Bone Marrow Transplant? **Yes or No**
b) Is the member premenopausal? **Yes or No**

□ **Gender Identity Disorder/Gender Incongruence or Gender Dysphoria**

For Adolescent Members:

a) Does the member have mental health disorders? **Yes or No**
- If **Yes,** are the mental health disorders reasonably well controlled? **Yes or No**
b) Has the member undergone surgery for gender reassignment (e.g. gonadectomy)? **Yes or No**
c) Will the member be social support during treatment? **Yes or No**

For Adult Members:

a) Does the member have mental health disorders? **Yes or No**
- If **Yes,** are the mental health disorders reasonably well controlled? **Yes or No**
b) Has the member undergone surgery for gender reassignment (e.g. gonadectomy)? **Yes or No**

□ **Menorrhagia (Heavy bleeding)/ Excessive or frequent menstruation**

a) How many total weeks of therapy has the member previously received of the requested drug? _____
b) What is the heavy bleeding associated with? (If it is due to one of the listed diagnoses, please also choose that diagnosis and answer related questions).
_____
e) What is the member's menopausal status? □ Premenopausal □ Perimenopausal □ Postmenopausal
f) Will the member be taking any other drugs for this diagnosis? **Yes or No** If yes, please list the specific drug:
_____

□ **Other**: _____

Physician office's signature*_____ Print Name_____
***Form must be completed and signed by physician or licensed representative from the physician's office**.