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

Drug Name: _____ Strength: _____ Directions: _____

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

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

Horizon NJ Health
Gonadotropin Releasing Hormones (GnRH) agonists and antagonists – Medical Necessity Request
Complete pages 1-7 for Initial Requests Only

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

Drug	Contraindication(s)
□ Goserelin (Zoladex 10.9mg) □ Goserelin (Zoladex 3.6mg) □ Histrelin (Supprelin LA) □ Leuprolide (Lupron Depot-Ped) □ Leuprolide (Fensolvi) □ Triptorelin (Triptodur)	□ Pregnancy □ NONE
□ Leuprolide (Lupron Depot 3.75mg) □ Leuprolide (Lupron Depot 11.25mg)	□ Pregnancy □ Undiagnosed abnormal uterine bleeding □ NONE
□ Leuprolide 65 mg implant (Viadur)	□ Pregnancy □ Pediatric member □ NONE
□ Nafarelin (Synarel)	□ Pregnancy or in members who may become pregnant while on therapy □ Undiagnosed abnormal vaginal bleeding □ Members who are breast-feeding □ NONE
□ Elagolix (Orilissa)	□ Pregnancy □ Osteoporosis □ Severe liver impairment □ Taking organic anion transporting polypeptide (OATP) 1B1 inhibitors that significantly increase elagolix plasma concentrations □ NONE
□ Elagolix, estradiol, and noresthindrone acetate and Elagolix (Oriahnn)	□ Pregnancy □ Osteoporosis □ Known liver impairment □ Taking organic anion transporting polypeptide (OATP)1B1 inhibitors that are known or expected to significantly increase elagolix plasma concentrations □ High risk of arterial, venous thrombotic, or thromboembolic disorder □ Current or history of breast cancer or other hormonally-sensitive malignancies □ Undiagnosed abnormal uterine bleeding □ NONE
□ Relugolix, estradiol, and norethindrone acetate (Myfembree)	□ Pregnancy □ Osteoporosis □ Known liver impairment □ High risk of arterial, venous thrombotic, or thromboembolic disorder □ Current or history of breast cancer or other hormone-sensitive malignancies □ Undiagnosed abnormal uterine bleeding □ NONE

Continued on p. 2

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: _____

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

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

Diagnosis Information: Please select diagnosis and answer related questions.

□ Precocious Puberty

1. Is the precocious puberty either true or central? **Yes or No**
2. Has tumor been ruled out by appropriate diagnostic procedure? **Yes or No**
3. Does the member have an onset of secondary sexual characteristics that occurred at or before age 9? **Yes or No**
4. 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**
    a. If **Yes**, does the member have any of the following (please select all that apply)?:
        □ 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
5. For **Fensolvi, Supprelin LA or Triptodur** requests, please also answer these additional questions:
    a. Can the member try any of the following drug(s) instead: Lupron Depot-Ped or Synarel Nasal Spray?. **Yes or No**
        i. If **Yes**, please let us know which drug can be tried and the strength/directions:
        _____
        ii. 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]:
        _____

□ Gender Identity Disorder/Gender Incongruence or Gender Dysphoria

1. For **Adolescent** members:
    a. Does the member have mental health disorders? **Yes or No**
        i. 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 receiving 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**
2. For **Adult** members:
    a. Does the member have mental health disorders? **Yes or No**
        i. 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**

Continued on p. 3

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: _____

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

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

□ Endometriosis

1. How many total weeks/months of therapy has the member previously received of the requested drug?
   _____
2. For **Orilissa** requests, please also answer these additional questions:
   a. Can the member try any of the following drug(s) instead?: Lupron Depot 3.75mg or 11.25mg, Synarel Nasal Spray, Zoladex 3.6mg, or Depo-SubQ Provera 104. **Yes or No**
      i. If **Yes**, please let us know which drug can be tried and the strength/directions, and let us know many total weeks/months of therapy the member has previously received:
      _____
      ii. 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]:
      _____
   b. Does the member have pain? **Yes or No**
      i. If **Yes**, what is the severity of the pain? □ Mild □ Moderate □ Severe
   c. Does the member have dyspareunia? **Yes or No**
   d. Does the member have moderate hepatic impairment (Child-Pugh Class B)? **Yes or No**
   e. Will the member be using Oriahnn concurrently? **Yes or No**
   f. What is the total length of therapy requested?: _____
3. For **Myfembree** requests, please also answer these additional questions:
   a. Can the member try any of the following drug(s) instead?: Lupron Depot 3.75mg or 11.25mg, Synarel Nasal Spray, Zoladex 3.6mg, or Depo-SubQ Provera 104. **Yes or No**
      i. If **Yes**, please let us know which drug can be tried and the strength/directions, and let us know many total weeks/months of therapy the member has previously received:
      _____
      ii. 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]:
      _____
   b. Does the member have pain? **Yes or No**
      i. If **Yes**, what is the severity of the pain? □ Mild □ Moderate □ Severe
   c. What is the member's menopausal status? □ Premenopausal □ Perimenopausal □ Postmenopausal

□ Dysfunctional (Abnormal) Uterine Bleeding

1. Will the member be undergoing surgery (endometrial ablation)? **Yes or No**
2. 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) _____
3. How many depot injections will the member receive before surgery (endometrial ablation)? _____
4. Once depot injections are given, after how many weeks will surgery be performed? _____

Continued on p. 4

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: _____

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

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

□ Uterine Fibroids (Leiomyomata)

1. Does the member have anemia due to the fibroids? **Yes or No**
2. Will the member be undergoing surgery for the fibroids? **Yes or No**
3. Has the member tried iron therapy? **Yes or No**
    a. If **Yes**, please let us how long was the member on iron therapy: _____
    b. If **No**, please let us know why the member has not tried iron therapy: _____
4. Did the member respond to iron therapy alone? **Yes or No**
    a. If **No**, please let us know the specific reason for failure:
    _____
5. Will the member be receiving iron with the requested drug? **Yes or No**
    a. If **No**, please let us know why not: _____
6. Does the member have heavy menstrual bleeding associated with the fibroids? **Yes or No**
    a. If **Yes**, please also answer questions for Menorrhagia (Heavy bleeding)/Excessive or frequent menstruation diagnosis

□ Menorrhagia (Heavy bleeding)/Excessive or frequent menstruation

1. How many total weeks/months of therapy has the member previously received of the requested drug?
    _____
2. 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) _____
3. What is the member's menopausal status? □ Premenopausal □ Perimenopausal □ Postmenopausal
4. For **Myfembree** requests, please also answer these additional questions:
    a. Can the member try any of the following drug(s) instead: Oriahnn? **Yes or No**
        i. If **Yes**, please let us know which drug can be tried and let us know many total weeks/months of therapy the member has previously received:
        _____
        ii. 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]:
        _____
5. For **Oriahnn** requests, please also answer these additional questions:
    a. Will the member be using Orilissa concomitantly? **Yes or No**

□ Breast Cancer

1. Is the requested drug being used for the palliative treatment of advanced disease? **Yes or No**
2. What is the member's menopausal status? □ Premenopausal □ Perimenopausal □ Postmenopausal
3. Does the member have hormone receptor-positive disease? **Yes or No**
4. Will the requested drug be given in combination with adjuvant endocrine therapy (e.g., tamoxifen)? **Yes or No**
5. Does the member have recurrent unresectable (local or regional) or stage IV (M1) disease? **Yes or No**
    a. If **Yes**, will the requested drug be given in combination with endocrine therapy? **Yes or No**
6. Please provide any additional information about the member's disease state:
    _____
    _____

Continued on p. 5

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: _____

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

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

□ Ovarian Cancer

1. Does the member have any of the following (please select all that apply):
   □ Grade 1 Endometroid Carcinoma, Stage IC or Stage II-IV disease
   □ Low-grade Serous Carcinoma, Stage IC or Stage II-IV disease
   □ Malignant Sex Cord-Stromal Tumor, specifically for clinical relapse of Stage II-IV granulosa cell tumors
   □ None of the above
2. Does the member have persistent or recurrent disease? **Yes or No**
   a. If **Yes**, does the member have any of the following (please select all that apply)?:
      □ Epithelial Ovarian Cancer
      □ Fallopian Tube Cancer
      □ Primary Peritoneal Cancer
      □ Grade 1 Endometroid Carcinoma
      □ Low-grade Serous Carcinoma (if an aromatase inhibitor was given previously)
      □ Mucinous Carcinoma of the Ovary
      □ Clear Cell Carcinoma of the Ovary
      □ Carcinosarcoma (Malignant Mixed Müllerian Tumors)
      □ None of the above
3. Please provide any additional information about the member's disease state:
   _____
   _____

□ Ovarian Protection during Chemotherapy

1. Will the drug be administered while receiving chemotherapy treatment? **Yes or No**
2. What is the member's menopausal status? □ Premenopausal □ Perimenopausal □ Postmenopausal

□ Suppression of Menstruation or Ovarian Protection during Transplant

1. Will the member be undergoing bone marrow transplant? **Yes or No**
2. What is the member's menopausal status? □ Premenopausal □ Perimenopausal □ Postmenopausal

□ Prostate Cancer

1. For **Eligard, Firmagon, Lupron, Lupron Depot, Trelstar or Zoladex** requests, no additional criteria – submit fax form
2. For **Camcevi** requests, please also answer these additional questions:
   a. Can the member try any of the following drug(s) instead?: Eligard, Firmagon, Lupron, Lupron Depot, Trelstar or Zoladex. **Yes or No**
      i. If **Yes**, please let us know which drug can be tried and the strength/directions, and submit fax form:
      _____
      ii. 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]:
      _____
3. For **Viadur** requests, also answer these additional questions:
   a. Is the drug being used for the palliative treatment of advanced prostate cancer? **Yes or No**

Continued on p. 6

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: _____

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

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

4. For **Vantas** requests, also answer these additional questions:
    a. Is the drug being used for the palliative treatment of advanced prostate cancer? **Yes or No**
    b. Can the member try any of the following drug(s) instead?: Eligard, Lupron, or Zoladex. **Yes or No**
        i. If **Yes**, please let us know which drug can be tried and the strength/directions, and submit fax form:
        _____
        ii. 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]:
        _____
5. For all other requests, also answer these additional questions:
    a. Does the member have advanced prostate cancer? **Yes or No**
    b. Does the member have castration-sensitive disease? **Yes or No**
    c. Has the member's cancer progressed on observation of localized disease? **Yes or No**
    d. Does the member have M0 disease and life expectancy > 5 years? **Yes or No**
        i. If **Yes**, please select which of the following applies:
        □ Prostate-specific antigen (PSA) persistence/recurrence after radical prostatectomy in combination with external beam radiation therapy (EBRT) if studies negative for distant metastatic disease and pelvic recurrence or imaging not performed
        □ PSA persistence/recurrence after radical prostatectomy in combination with EBRT if studies are positive for pelvic recurrence
        □ PSA recurrence or positive digital rectal examination (DRE) after EBRT if biopsy negative or not performed, and studies negative for distant metastatic disease
        □ PSA recurrence or positive DRE after EBRT if studies positive for pelvic recurrence
        □ None of the above
    e. Will the requested drug be taken with external beam radiation therapy (EBRT) AND does the member have life expectancy >5 years or symptomatic? **Yes or No**
        i. If **Yes**, please select which of the following applies:
        □ For 4-6 months with or without brachytherapy for members in the unfavorable intermediate-risk group
        □ For 1.5-3 years for members in the high- or very-high-risk group
        □ For 1-3 years in combination with brachytherapy for members in the high- or very-high-risk group
        □ For members in the regional risk group (Any T, N1, M0)
        □ None of the above
    f. Was lymph node metastasis found during pelvic lymph node dissection (PLND)? **Yes or No**
        i. If **Yes**, please select which of the following applies:
        □ In the intermediate-risk group and >10 year expected survival
        □ In the high- or very-high-risk groups and >5 year expected survival or symptomatic
        □ In the regional risk group (Any T, N1, M0) and >5 year expected survival or symptomatic
        □ None of the above

Continued on p. 7

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

g. Does the member have life expectancy ≤5 years? **Yes or No**
   i. If **Yes**, please select which of the following applies:
      □ Symptomatic with very low-, low-, and intermediate-risk disease
      □ Asymptomatic with high- or very- high-risk disease where complications such as hydronephrosis or metastasis can be expected within 5 years
      □ Asymptomatic in members with regional risk disease (Any T, N1, M0)
      □ None of the above

h. Will the requested drug be taken with external beam radiation therapy (EBRT) if adverse features (i.e. positive margins, seminal vesicle invasion, extracapsular extension, or detectable PSA) were noted after radical prostatectomy (RP)? **Yes or No**
   i. If **Yes**, please select which of the following applies:
      □ In the very-low-risk group and >20 year expected survival
      □ In the low-risk group and ≥10 year expected survival
      □ No lymph node metastases in the favorable intermediate-risk group and >10 year expected survival
      □ With pelvic lymph node dissection (PLND) and no lymph node metastases in the unfavorable intermediate-risk group and >10 year expected survival
      □ With PLND and no lymph node metastases in the high-risk, very-high-risk, or regional risk group (Any T, N1, M0) and >5 year expected survival or symptomatic
      □ None of the above

6. Please provide any additional information about the member's disease state:
   _____
   _____

□ Salivary Gland Tumors

1. Does the member have androgen receptor positive recurrent disease? **Yes or No**
   a. If **Yes**, please select which of the following applies:
      □ Distant metastases in members with a performance status (PS) of 0-3
      □ Unresectable locoregional recurrence or second primary with prior radiation therapy
      □ None of the above

□ 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: _____

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

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

Horizon NJ Health
Gonadotropin Releasing Hormones (GnRH) agonists and antagonists – Medical Necessity Request
Complete pages 8-9 for Subsequent/Renewal Requests Only

Diagnosis Information: Please select diagnosis and answer related questions if applicable.

□ Precocious Puberty

□ Gender Identity Disorder/Gender Incongruence or Gender Dysphoria

1. For **Adolescent** members:
    a. Does the member have mental health disorders? **Yes or No**
        i. 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 receiving social support during treatment? **Yes or No**
2. For **Adult** members:
    a. Does the member have mental health disorders? **Yes or No**
        i. 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**

□ Endometriosis

1. How many total weeks/months of therapy has the member previously received of the requested drug?
   _____
2. For **Lupron Depot, Zoladex or Synarel** requests, please also answer these additional questions:
    a. Have symptoms recurred after 6 months of therapy? **Yes or No**
    b. Will the member be concomitantly receiving Norethindrone? **Yes or No**
3. For **Orilissa** requests, please also answer these additional questions:
    a. Does the member have pain? **Yes or No**
        i. If **Yes**, what is the severity of the pain? □ Mild □ Moderate □ Severe
    b. Does the member have dyspareunia? **Yes or No**
    c. Does the member have moderate hepatic impairment (Child-Pugh Class B)? **Yes or No**
    d. Will the member be using Oriahnn concurrently? **Yes or No**
    e. What is the total length of therapy requested?: _____
4. For **Myfembree** requests, please also answer these additional questions:
    a. Does the member have pain? **Yes or No**
        i. If **Yes**, what is the severity of the pain? □ Mild □ Moderate □ Severe
    b. What is the member's menopausal status? □ Premenopausal □ Perimenopausal □ Postmenopausal

Continued on p. 9

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: _____

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

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

□ Menorrhagia (Heavy bleeding)/Excessive or frequent menstruation

1. How many total weeks/months of therapy has the member previously received of the requested drug? _____
2. 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) _____
3. What is the member's menopausal status? □ Premenopausal □ Perimenopausal □ Postmenopausal
4. For **Oriahnn** requests, please also answer these additional questions:
    a. Will the member be using Orilissa concomitantly? **Yes or No**

□ Breast Cancer

1. Is the requested drug being used for the palliative treatment of advanced disease? **Yes or No**
2. What is the member's menopausal status? □ Premenopausal □ Perimenopausal □ Postmenopausal
3. Does the member have hormone receptor-positive disease? **Yes or No**
4. Will the requested drug be given in combination with adjuvant endocrine therapy (e.g., tamoxifen)? **Yes or No**
5. Does the member have recurrent unresectable (local or regional) or stage IV (M1) disease? **Yes or No**
    a. If **Yes**, will the requested drug be given in combination with endocrine therapy? **Yes or No**

□ Ovarian Cancer

□ Ovarian Protection during Chemotherapy

1. Will the drug be administered while receiving chemotherapy treatment? **Yes or No**
2. What is the member's menopausal status? □ Premenopausal □ Perimenopausal □ Postmenopausal

□ Suppression of Menstruation or Ovarian Protection during Transplant

1. What is the member's menopausal status? □ Premenopausal □ Perimenopausal □ Postmenopausal

□ Prostate Cancer

□ Salivary Gland Tumors

□ Other: _____

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