AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Eligard	Page:	1 of 3
Effective Date:	8/19/2024	Last Review Date:	7/2024

Applies to:	☒Illinois	☐Florida	☒New Jersey
	☐Maryland	☐Michigan	☐Florida Kids
	☒Pennsylvania Kids	☐Virginia	☒Kentucky PRMD

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Eligard under the patient's prescription drug benefit.

Description:

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication
Palliative treatment of advanced prostate cancer

B. Compendial Uses
1. Prostate cancer
2. Recurrent androgen receptor positive salivary gland tumors
3. Gender Dysphoria (also known as gender non-conforming or transgender persons)

All other indications are considered experimental/investigational and not medically necessary.

Per state regulatory guidelines around gender dysphoria, age restrictions may apply.

Applicable Drug List:

Eligard

Policy/Guideline:

Prescriber Specialty:
For gender dysphoria, the medication must be prescribed by or in consultation with a provider specialized in the care of transgender youth (e.g., pediatric endocrinologist, family or internal medicine physician, obstetrician-gynecologist) that has collaborated care with a mental health provider for patients less than 18 years of age.

Criteria for Initial Approval:

A. Prostate cancer
Authorization of 12 months may be granted for treatment of prostate cancer.

B. Gender dysphoria
1. Authorization of 12 months may be granted for pubertal hormonal suppression in an adolescent member when all of the following criteria are met:
   i. The member has a diagnosis of gender dysphoria.
   ii. The member is able to make an informed decision to engage in treatment.

iii. The member has reached Tanner stage 2 of puberty or greater.
iv. The member's comorbid conditions are reasonably controlled.
v. The member has been educated on any contraindications and side effects to therapy.
vi. The member has been informed of fertility preservation options.

2. Authorization of 12 months may be granted for gender transition when all of the following criteria are met:
   i. The member has a diagnosis of gender dysphoria.
   ii. The member is able to make an informed decision to engage in treatment.
   iii. The member will receive Eligard concomitantly with gender-affirming hormones.
   iv. The member's comorbid conditions are reasonably controlled.
   v. The member has been educated on any contraindications and side effects to therapy.
   vi. The member has been informed of fertility preservation options.

C. Salivary gland tumors

Authorization of 12 months may be granted for treatment of recurrent, unresectable, or metastatic salivary gland tumors as a single agent when the tumor is androgen receptor positive.

Continuation of Therapy:

A. Salivary gland tumors

Authorization of 12 months may be granted for continued treatment of salivary gland tumors in members requesting reauthorization who are experiencing clinical benefit to therapy and who have not experienced an unacceptable toxicity.

B. Prostate cancer

Authorization of 12 months may be granted for continued treatment of prostate cancer in members requesting reauthorization who are experiencing clinical benefit to therapy (e.g., serum testosterone less than 50 ng/dL) and who have not experienced an unacceptable toxicity.

C. Gender Dysphoria

1. Authorization of 12 months may be granted for continued treatment for pubertal hormonal suppression in adolescent members requesting reauthorization when all of the following criteria are met:
   i. The member has a diagnosis of gender dysphoria.
   ii. The member is able to make an informed decision to engage in treatment.
   iii. The member has previously reached Tanner stage 2 of puberty or greater.
   iv. The member's comorbid conditions are reasonably controlled.

v. The member has been educated on any contraindications and side effects to therapy.
vi. Before the start of therapy, the member has been informed of fertility preservation options.

2. Authorization of 12 months may be granted for continued treatment for gender transition in members requesting reauthorization when all of the following criteria are met:
   i. The member has a diagnosis of gender dysphoria.
   ii. The member is able to make an informed decision to engage in treatment.
   iii. The member will receive Eligard concomitantly with gender-affirming hormones.
   iv. The member's comorbid conditions are reasonably controlled.
   v. The member has been educated on any contraindications and side effects to therapy.
   vi. Before the start of therapy, the member has been informed of fertility preservation options.

Approval Duration and Quantity Restrictions:

Approval: 12 months

References:

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4. Gender Identity Research and Education Society. Guidance for GPs and other clinicians on the treatment of gender variant people. UK Department of Health. Published March 10, 2008.
5. Coleman E, Radix AE, Brown GR, et al. Standards of care for the health of transgender and gender diverse people, version 8. 2022;23(Suppl 1):S1-S259. doi: 10.1080/26895269.2022.2100644
6. Mahfouda S, Moore JK, Siafarikas A, et al. Puberty suppression in transgender children and adolescents. *Lancet Diabetes Endocrinol*. 2017;5:816-26.
7. Health Care for Transgender and Gender Diverse Individuals. ©2021 The American College of Obstetricians and Gynecologists. Available at: https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2021/03/health-care-for-transgender-and-gender-diverse-individuals.
8. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Head and Neck Cancers. Version 2. 2024. Accessed February 15, 2024. https://www.nccn.org/professionals/physician_gls/pdf/head-and-neck.pdf.