09-J1000-04

Original Effective Date: 05/15/09

Reviewed: 05/14/14

Revised: 10/01/16

Subject: Fulvestrant (Faslodex®) IM

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

Fulvestrant (Faslodex), a pure estrogen-receptor antagonist, works by downregulating estrogen receptors. Fulvestrant was initially approved in April 2002 as second-line treatment of advanced breast cancer in post-menopausal women. Other compendia-supported indications include first-line treatment of breast cancer in post-menopausal women, subsequent therapy in pre-menopausal women receiving concomitant ovarian suppression/ablation, and in men with breast cancer who are receiving concomitant testicular steroidogenesis.

POSITION STATEMENT:

Fulvestrant (Faslodex®) IM **meets the definition of medical necessity** when used to treat metastatic breast cancer when the following criteria are met:

1. The dose does not exceed either of the following:
    a. Initial dose: 1500 mg in 29 days (i.e., 500 mg on days 1, 15, 29)
    b. Maintenance dose: 500 mg every 28 days
2. **ANY** of the following:
    a. The member is a post-menopausal female
    b. The member is a pre-menopausal female, is treated with ovarian ablation/suppression, and fulvestrant will be used in a subsequent line of therapy (i.e., not first line)

c. The member is male and will receive concomitant suppression of testicular steroidogenesis

Approval duration: 1 year

DOSAGE/ADMINISTRATION:

THIS INFORMATION IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY AND SHOULD NOT BE USED AS A SOURCE FOR MAKING PRESCRIBING OR OTHER MEDICAL DETERMINATIONS. PROVIDERS SHOULD REFER TO THE MANUFACTURER'S FULL PRESCRIBING INFORMATION FOR DOSAGE GUIDELINES AND OTHER INFORMATION RELATED TO THIS MEDICATION BEFORE MAKING ANY CLINICAL DECISIONS REGARDING ITS USAGE.

FDA-approved: fulvestrant is indicated for the treatment of hormone receptor positive metastatic breast cancer in post-menopausal women with disease progression following anti-estrogen therapy. The recommended initial dose is 500 mg on days 1, 15, and 29; the recommended maintenance dose is 500 mg every 28 days. Fulvestrant should be administered intramuscularly into the buttocks (over 1-2 minutes per injection) as two 5 mL injection (one in each buttock).

In persons with moderate hepatic impairment, the dose should be reduced to 250 mg on days 1, 15, and 29 and once monthly therafter.

Product Availability: fulvestrant is supplied as a 50 mg/ml injection.

PRECAUTIONS:

Contraindications:

Hypersensitivity to the drug or any of its components. Hypersensitivity reactions, including urticaria and angioedema, have been reported in association with fulvestrant.

Warnings:

Bleeding tendencies: Because fulvestrant is administered intramuscularly, it should not be used in members with bleeding diatheses, thrombocytopenia or members on anticoagulants.

Hepatic function impairment: Refer to Dosage/Administration section.

Use in Pregnancy: Fulvestrant can cause fetal harm when administered to a pregnant woman. Women of childbearing potential should be advised not to become pregnant while receiving fulvestrant.

BILLING/CODING INFORMATION:

The following codes may be used to describe:

HCPCS Coding:

J9395	Injection, Fulvestrant, 25 mg

ICD-10 Diagnosis Codes That Support Medical Necessity:

C50.011 – C50.929	Malignant neoplasm of breast

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage Products: No National Coverage Determination (NCD) was found at the time of the last guideline revised date. The following Local Coverage Determination (LCD) was reviewed on the last guideline revised date: Fulvestrant (Faslodex®), (L33998) located at fcso.com.

DEFINITIONS:

No guideline specific definitions apply.

RELATED GUIDELINES:

Carboplatin (Paraplatin®) Injection, 09-J0000-93

Docetaxel (Taxotere®) IV, 09-J0000-95

Oxaliplatin (Eloxatin®) Injection, 09-J1000-00

OTHER:

None applicable.

REFERENCES:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.;2012. URL www.clinicalpharmacilogy-ip.com Accessed 4/14/14.
2. Faslodex (fulvestrant) [package insert]. AstraZeneca Pharmaceuticals. Wilmington (DE): November 2012.
3. Fulvestrant. In McEvoy GK, editor. AHFS drug information 2014 [monograph on the internet]. Bethesda (MD): American Society of Health-System Pharmacists; 2014 [cited 2014 Apr 14]. Available from http://online.statref.com Subscription required to review.
4. Ingenix HCPCS Level II, Expert 2014.
5. Ingenix ICD-9-CM for Physicians-Volumes 1 & 2, Expert 2014
6. Micromedex® Healthcare Series [Internet Database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed 4/14/14.

7. National Comprehensive Cancer Network. Cancer Guidelines. Cancer Guidelines and Drugs and Biologics Compendium. Accessed 4/14/14

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Committee on 05/14/14.

GUIDELINE UPDATE INFORMATION:

05/15/09	New Medical Coverage Guideline.
01/15/10	Revision to guideline; consisting of updating dosage.
08/01/10	Revision to guideline; consisting of updating coding.
11/15/10	Review and revision to guideline; consisting of increasing dosage maximum, updating coding and references.
08/17/11	Revision; ICD-10 codes updated.
11/15/11	Review and revision to guideline; consisting of updating references.
11/15/12	Review and revision to guideline; consisting of reformatting position statement and updating references.
06/15/13	Review and revision to guideline; consisting of updating position statement, dosage and administration, precautions, program exceptions and references.
06/15/14	Review and revision to guideline; consisting of revising and reformatting position statement, reformatting dosage/administration, precautions sections, updating references.
10/01/15	Revision consisting of update to Program Exceptions section.
11/01/15	Revision: ICD-9 Codes deleted.
10/01/16	Revision to guideline; consisting of updating ICD10 code