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AstraZeneca

FASLODEX Coding Resource

US-21918

Coding Resource

Indications for FASLODEX

Monotherapy

FASLODEX is an estrogen receptor antagonist indicated for the:

- Treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer in postmenopausal women not previously treated with endocrine therapy
- Treatment of HR-positive advanced breast cancer in postmenopausal women with disease progression following endocrine therapy

Combination Therapy

- FASLODEX in combination with palbociclib or abemaciclib is indicated for the treatment of HR-positive, HER2-negative advanced or metastatic breast cancer in women with disease progression after endocrine therapy

It is important to note that the codes identified below are examples only. Each provider is responsible for ensuring all coding is accurate and documented in the medical record based on the condition of the patient. The use of the following codes does not guarantee reimbursement.

National Drug Code (NDC)

10-digit NDC

Dosage	Code
250 mg/5 mL	0310-0720-10

11-digit NDC

Dosage	Code
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Current Procedural Terminology® (CPT)[1]

Submitting accurate codes and claims is important to ensure proper reimbursement of services. The chart below lists the POTENTIAL CPT code for your reference when submitting claims for FASLODEX.

Code	Description
96402	Chemotherapy administration, subcutaneous or intramuscular; hormonal antineoplastic

Healthcare Common Procedure Coding System (HCPCS)[2]

Code	Description	Vial Size	Billing Units
J9395	Injection, fulvestrant, 25 mg	250 mg/5 mL	10 Units

Please see Important Safety Information on pages 5-6, and accompanying full Prescribing Information with Patient Information.

Coding Resource

Diagnosis Codes[3]

ICD-10-CM	Description
MALIGNANT NEOPLASMS OF BREAST	
C50.011	Malignant neoplasm of nipple and areola, right female breast
C50.012	Malignant neoplasm of nipple and areola, left female breast
C50.019	Malignant neoplasm of nipple and areola, unspecified female breast
C50.111	Malignant neoplasm of central portion of right female breast
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C50.119	Malignant neoplasm of central portion of unspecified female breast
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C50.512	Malignant neoplasm of lower-outer quadrant of left female breast
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C50.611	Malignant neoplasm of axillary tail of right female breast
C50.612	Malignant neoplasm of axillary tail of left female breast
C50.619	Malignant neoplasm of axillary tail of unspecified female breast
C50.811	Malignant neoplasm of overlapping sites of right female breast

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ICD-10-CM	Description
MALIGNANT NEOPLASMS OF BREAST	
C50.812	Malignant neoplasm of overlapping sites of left female breast
C50.819	Malignant neoplasm of overlapping sites of unspecified female breast
C50.911	Malignant neoplasm of unspecified site of right female breast
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C50.919	Malignant neoplasm of unspecified site of unspecified female breast
PERSONAL HISTORY OF MALIGNANT NEOPLASM OF BREAST	
Z85.3	Personal history of malignant neoplasm of breast

Coding Resource

IMPORTANT SAFETY INFORMATION

Contraindications

- FASLODEX is contraindicated in patients with known hypersensitivity to the drug or to any of its components. Hypersensitivity reactions, including urticaria and angioedema, have been reported in association with FASLODEX

Risk of Bleeding

- Because FASLODEX is administered intramuscularly, it should be used with caution in patients with bleeding diatheses, thrombocytopenia, or anticoagulant use

Hepatic Impairment

- FASLODEX is metabolized primarily in the liver. A 250 mg dose is recommended in patients with moderate hepatic impairment (Child-Pugh class B). FASLODEX has not been evaluated in patients with severe hepatic impairment (Child-Pugh class C)

Injection Site Reaction

- Use caution while administering FASLODEX at the dorsogluteal injection site due to the proximity of the underlying sciatic nerve. Injection site–related events, including sciatica, neuralgia, neuropathic pain, and peripheral neuropathy, have been reported with FASLODEX injection

Embryo-Fetal Toxicity and Lactation

- Advise pregnant women of the potential risk to a fetus. Advise women of reproductive potential to use effective contraception during FASLODEX treatment and for 1 year after the final dose. Advise lactating women not to breastfeed during treatment with FASLODEX and for 1 year after the final dose because of the potential risk to the infant

Immunoassay Measurement of Serum Estradiol

- Due to structural similarity of fulvestrant and estradiol, FASLODEX can interfere with estradiol measurement by immunoassay, resulting in falsely elevated estradiol levels

Adverse Reactions

Monotherapy

- The most common adverse reactions occurring in ≥5% of patients receiving FASLODEX 500 mg were injection site pain, nausea, bone pain, arthralgia, headache, back pain, fatigue, pain in extremity, hot flash, myalgia, vomiting, anorexia, diarrhea, asthenia, musculoskeletal pain, cough, dyspnea, and constipation
- Increased hepatic enzymes (ALT, AST, ALP) occurred in >15% of FASLODEX patients and were not dose-dependent

Combination Therapy—FASLODEX plus palbociclib

- The most frequently reported Grade ≥3 adverse reactions in patients receiving FASLODEX plus palbociclib in descending frequency were neutropenia and leukopenia
- Adverse reactions (≥10%) of any grade reported in patients receiving FASLODEX 500 mg plus palbociclib 125 mg/day by descending frequency were neutropenia, leukopenia, infections, fatigue, nausea, anemia, stomatitis, diarrhea, thrombocytopenia, vomiting, alopecia, rash, decreased appetite, and pyrexia
- Additional adverse reactions occurring at an overall incidence of <10% of patients receiving FASLODEX plus palbociclib included asthenia, aspartate aminotransferase increased, dysgeusia, epistaxis, lacrimation increased, dry skin, alanine aminotransferase increased, vision blurred, dry eye, and febrile neutropenia

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IMPORTANT SAFETY INFORMATION (CONT'D)

Combination Therapy—FASLODEX plus abemaciclib

- The most frequently reported (≥5%) Grade 3 or 4 adverse reactions in patients receiving FASLODEX plus abemaciclib were neutropenia, diarrhea, leukopenia, anemia, and infections
- The most common adverse reactions (≥20%) of any grade reported in patients receiving FASLODEX 500 mg plus abemaciclib 150 mg twice daily were diarrhea, fatigue, neutropenia, nausea, infections, abdominal pain, anemia, leukopenia, decreased appetite, vomiting, and headache

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Combination Therapy

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You are encouraged to report negative side effects of AstraZeneca prescription drugs by calling 1-800-236-9933. If you prefer to report these to the FDA, either visit www.FDA.gov/medwatch or call 1-800-FDA-1088.

For more information, call AstraZeneca Access 360™ at **1-844-ASK-A360**, Monday through Friday, 8 AM to 8 PM ET.

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www.MyAccess360.com

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One MedImmune Way, Gaithersburg, MD 20878

References: 1. American Medical Association. CPT® 2017 Professional Edition. Chicago, IL: American Medical Association; 2017. **2.** Centers for Medicare & Medicaid Services. HCPCS Release & Code Sets. https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS.html. Accessed June 20, 2018. **3.** American Medical Association. ICD-10-CM 2017: The Complete Official Codebook. Chicago, IL: American Medical Association; 2017.

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FASLODEX® fulvestrant injection | AstraZeneca Access 360™

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