IRESSA®
gefitinib

Coding Resource

1-844-ASK-A360
1-844-275-2360

1-844-FAX-A360
1-844-329-2360

www.MyAccess360.com

For more information, call Access 360™ at 1-844-ASK-A360, Monday through Friday, 8:00 AM to 8:00 PM ET.

IRESSA is indicated for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test.

Limitation of Use: Safety and efficacy of IRESSA have not been established in patients with metastatic NSCLC whose tumors have EGFR mutations other than exon 19 deletions or exon 21 (L858R) substitution mutations.

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)

The National Drug Code (NDC) is a universal, unique, 3-segment number identifying drugs by manufacturer, dosage, and package size. Payers may require the submission of the 11-digit NDC on health care claim forms, and electronic claims may be denied for drugs billed without a valid 11-digit NDC. Contact your patient's health plan to determine claim submission requirements and to determine accurate reporting of NDC codes.

10-digit NDC

Dosage	Code
250 mg	0310-0482-30

11-digit NDC

Dosage	Code
250 mg	00310-0482-30

Important Safety Information about IRESSA

- Interstitial Lung Disease (ILD) or ILD-like reactions (eg, lung infiltration, pneumonitis, acute respiratory distress syndrome, or pulmonary fibrosis) occurred in 1.3% of 2462 IRESSA patients; of these, 0.7% were Grade ≥3 and 3 cases were fatal. Withhold IRESSA and promptly investigate for ILD in any patient who presents with worsening of respiratory symptoms such as dyspnea, cough and fever. Permanently discontinue IRESSA if ILD is confirmed
- In patients who received IRESSA, 11.4% of patients had increased alanine aminotransferase (ALT), 7.9% of patients had increased aspartate aminotransferase (AST), and 2.7% of patients had increased bilirubin. Grade ≥3 liver test abnormalities occurred in 5.1% ALT, 3.0% AST, and 0.7% bilirubin of patients. The incidence of fatal hepatotoxicity was 0.04%. Obtain periodic liver function testing. Withhold IRESSA in patients with worsening liver function and discontinue in patients with severe hepatic impairment

Please read Important Safety Information on page 4 and SEE ACCOMPANYING FULL PRESCRIBING INFORMATION.

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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 Current Procedural Terminology (CPT) code for your reference when submitting claims for your IRESSA patients.

Code	Description
81235	EGFR (epidermal growth factor receptor) (eg, non-small cell lung cancer) gene analysis, common variants (eg, exon 19 LREA deletion, L858R, T790M, G719A, G719S, L861Q)

Healthcare Common Procedure Coding System (HCPCS)[2]

Submitting accurate codes and claims is important to ensure proper reimbursement of services. The chart below lists potential code(s) for your reference when submitting claims for your IRESSA patients.

Code	Description
G0452	Molecular pathology procedure; physician interpretation and report

Diagnosis Codes

When filing claims, providers often indicate a diagnosis code reflecting the patient's condition. Based on the indications for IRESSA, examples of diagnosis codes that may be appropriate are listed below.

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.

International Classification of Diseases, Tenth Revision, Clinical Modification = ICD-10-CM

ICD-10-CM	Description
C34.0	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus

Important Safety Information about IRESSA

- Gastrointestinal perforation occurred in three (0.1%) of 2462 IRESSA patients. Permanently discontinue IRESSA in patients who develop gastrointestinal perforation
- Grade ≥3 diarrhea occurred in 3% of 2462 IRESSA patients. Withhold IRESSA for severe or persistent (up to 14 days) diarrhea
- Ocular disorders [keratitis (0.1%), corneal erosion and aberrant eyelash growth (0.2%), conjunctivitis, blepharitis and dry eye (6.7%)] occurred in 2462 IRESSA patients. The incidence of Grade 3 ocular disorders was 0.1%. Interrupt or discontinue IRESSA for severe or worsening ocular disorders

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Diagnosis Codes (continued)

ICD-10-CM	Description
C34.02	Malignant neoplasm of left main bronchus
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.8	Malignant neoplasm of overlapping sites of unspecified bronchus and lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.9	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung

Important Safety Information about IRESSA

- Bullous conditions including toxic epidermal necrolysis, Stevens Johnson syndrome and erythema multiforme have been reported from treatment with IRESSA. Erythema multiforme and dermatitis bullous have been reported in two patients (0.08%) across NSCLC trials. IRESSA treatment should be interrupted or discontinued if patients develop severe bullous, blistering or exfoliating conditions
- Based on its mechanism of action and data from animal reproduction studies IRESSA can cause fetal harm when administered to a pregnant woman. In animal reproductive studies, oral administration of gefitinib from organogenesis through weaning resulted in fetotoxicity and neonatal death at doses below the recommended human dose. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with IRESSA and for at least two weeks following completion of therapy

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Important Safety Information About IRESSA

- There are no contraindications for IRESSA
- Interstitial Lung Disease (ILD) or ILD-like reactions (eg, lung infiltration, pneumonitis, acute respiratory distress syndrome, or pulmonary fibrosis) occurred in 1.3% of 2462 IRESSA patients; of these, 0.7% were Grade ≥3 and 3 cases were fatal. Withhold IRESSA and promptly investigate for ILD in any patient who presents with worsening of respiratory symptoms such as dyspnea, cough and fever. Permanently discontinue IRESSA if ILD is confirmed
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- Advise women to discontinue breast-feeding during treatment with IRESSA
- The most commonly reported adverse drug reactions reported in more than 20% of patients and greater than placebo, were skin reactions (47%) and diarrhea (29%)

You are encouraged to report negative side effects of prescription drugs to the FDA.
Visit www.FDA.gov/medwatch or call 1-800-FDA-1088.

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SEE ACCOMPANYING FULL PRESCRIBING INFORMATION.

References:

1. https://ocm.amaassn.org/OCM/CPTRelativeValueSearch.do?state=&region=&searchType=&keyword=G0452, accessed July 13, 2015.
2. http://www.hipaaspace.com/Medical_Billing/Coding/Healthcare_Common_Procedure_Coding_System/HCPCS_Codes_Lookup.aspx, accessed July 13, 2015.

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