NEW HCPCS CODE FOR DOXIL® (doxorubicin HCl liposome injection)

Beginning July 1, 2012, healthcare providers administering DOXIL® and billing Medicare should begin using the temporary Healthcare Common Procedure Coding System (HCPCS) code that the Centers for Medicare & Medicaid Services (CMS) has assigned specific to DOXIL® (Q2048) and discontinue use of the code J9001. The new code descriptor is worded in a manner that distinguishes DOXIL® from other forms of liposomal doxorubicin. The coding change is summarized in the table below[1]:

Code for Medicare Claims Prior to July 1, 2012[2]	Description	Code for Medicare Claims Starting July 1, 2012[3]	Description
J9001	Injection, doxorubicin HCl, all lipid formulations, 10 mg	Q2048	Injection, doxorubicin HCl, liposomal, DOXIL®, 10 mg
		Q2049	Injection, doxorubicin HCl, liposomal, imported Lipodox, 10 mg

For a complete listing of the quarterly updates scheduled to become effective July 1, 2012, please visit: http://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS_Quarterly_Update.html.

Why did the code change?
CMS determined that the current code, J9001, was not specific enough to accurately differentiate DOXIL® from other forms of liposomal doxorubicin.

How does the new Q-code differ from the codes for other forms of liposomal doxorubicin?
Code Q2048 specifically describes DOXIL®, which is distributed by Janssen Products, LP.

Does the coding change apply to all payers, or just Medicare?
The coding change will apply to Medicare for dates of service on or after July 1, 2012. Private payers update their coding sets on varying schedules. Some will adopt the codes sooner than others. Providers should check with private or other non-Medicare payers before submitting claims to verify what HCPCS codes they will accept. DOXILine® (1-800-609-1083) can also help verify your patient's insurance benefits and determine what codes should be used to identify DOXIL®.

What is the difference between Q-codes and J-codes?
Both Q-codes and J-codes are considered HCPCS level II codes. The Q-codes are temporary HCPCS codes used to identify services such as drugs, biologicals, and other types of medical equipment or services that are not identified by permanent level II codes. Q-codes are also established when additional codes are needed for payer claims processing or operational purposes. J-codes are assigned as permanent HCPCS level II codes to describe drugs, biologicals, and other types of medical equipment or services.[4]

How does the new Q-code differ from the codes for other forms of liposomal doxorubicin?
CMS has changed the language in the descriptor of code Q2048 to specifically identify the brand DOXIL®, which differentiates it from other forms of liposomal doxorubicin.

Please see Important Safety Information on reverse side.

Please see accompanying full Prescribing Information, including Boxed Warning.

DOXILine® can be reached at 1-800-609-1083, Monday through Friday, from 8 AM to 8 PM ET.

Can providers continue to bill using the existing code (J9001) after July 1?
Providers should bill for DOXIL® using Q2048 for all Medicare claims with dates of service on or after July 1, 2012. Providers should check which code(s) are accepted before submitting claims to private or other non-Medicare payers. Failure to utilize the correct, temporary Q-codes may prevent reimbursement on submitted DOXIL® claims.

Will the change in the DOXIL® HCPCS code affect Medicare reimbursement?
No. DOXIL® has been assigned a separate Q-code that will differentiate this product from other forms of liposomal doxorubicin. Medicare reimbursement rates are expected to continue to be reflective of the average sales price (ASP) for DOXIL®.

Will the change in the DOXIL® code affect reimbursement rates from private payers?
We have no reason to think that a change in coding will affect payment. Providers should contact their individual payers to verify contracted reimbursement rates.

What management processes in my office or clinic will be affected by the coding change?
Persons in charge of filing claims will need to ensure that their billing software is able to submit claims using the new code for DOXIL®, Q2048.

Will the J-code be reinstated in the future?
CMS has indicated that it will address this issue in the months to come, but at this point, no final determinations have been made.

1. CMS, HCPCS - General Information. http://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/index.html. Accessed 05/08/2012.
2. CMS. 2012 ASP Drug Pricing Files.http://www.cms.gov/apps/ama/license.asp?file=/McrPartBDrugAvgSalesPrice/downloads/APR-2012-ASP-Pricing-File.zip. Accessed 05/08/2012.
3. CMS. HCPCS Quarterly Updates. http://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Downloads/Other-codes-effective-July-1-2012-.zip. Accessed 05/08/2012.
4. CMS. HCPCS Level II Coding Procedures. http://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/ HCPCSLevelIICodingProcedures7-2011.pdf. Accessed 05/08/2012.

DOXIL® (doxorubicin HCl liposome injection)

INDICATIONS AND IMPORTANT SAFETY INFORMATION

INDICATIONS

- DOXIL® is indicated for the treatment of patients with ovarian cancer whose disease has progressed or recurred after platinum-based chemotherapy
- DOXIL® in combination with VELCADE® (bortezomib) is indicated for the treatment of patients with multiple myeloma who have not previously received VELCADE® and have received at least one prior therapy

IMPORTANT SAFETY INFORMATION
BOXED WARNINGS

Cardiotoxicity, infusion reaction, myelosuppression, liver impairment, substitution

- The use of DOXIL® may lead to cardiac toxicity. Myocardial damage may lead to congestive heart failure and may occuras the total cumulative dose of doxorubicin HCl approaches 550 mg/m^2
  - Prior use of other anthracyclines or anthracenediones should be included in calculations of total cumulative dose
  - Cardiac toxicity may also occur at lower cumulative doses (400 mg/m^2) in patients with prior mediastinal irradiation or who are receiving concurrent cyclophosphamide therapy
- Acute infusion-related reactions including, but not limited to, flushing, shortness of breath, facial swelling, headache, chills, back pain, tightness in the chest or throat, and/or hypotension have occurred in up to 10% of patients treated with DOXIL®. In most patients, these reactions have resolved within several hours to a day once the infusion is terminated. In some patients, reactions resolved with slowing of the infusion rate
  - Serious and sometimes life-threatening or fatal allergic/anaphylactoid-like infusion reactions have occurred. Medications to treat such reactions, as well as emergency equipment, should be available for immediate use
  - The initial rate of infusion should be 1 mg/min to minimize the risk of infusion reactions
- Severe myelosuppression may occur
- DOXIL® dosage should be reduced in patients with impaired hepatic function
- Accidental substitution has resulted in severe side effects. Do not substitute for doxorubicin HCl on a mg per mg basis

CONTRAINDICATIONS

- Patients with a history of hypersensitivity reactions to a conventional doxorubicin formulation or the components of DOXIL®
- Nursing mothers

ADDITIONAL SAFETY INFORMATION

- Cardiac function should be carefully monitored
  - Congestive heart failure or cardiomyopathy may occur after discontinuation of anthracycline therapy
  - For patients with a history of cardiovascular disease, or if the results of cardiac monitoring indicate possible cardiac injury, the benefit of therapy must be weighed against the risk of myocardial injury
  - In the randomized multiple myeloma study, 25 patients (8%) in the VELCADE® arm and 42 patients (13%) in the DOXIL® plus VELCADE® arm experienced left ventricular ejection fraction decrease (defined as absolute decrease ≥15% over baseline or a ≥5% decrease below institutional lower limit of normal)
- Myelosuppression may occur; frequently monitor complete blood count (including platelet count), at least prior to each dose of DOXIL®
  - In patients with recurrent ovarian cancer, hematologic toxicity (based on platelet count or absolute neutrophil count) may require dose reduction or delay in administration of DOXIL®
  - In patients with multiple myeloma, hematologic toxicity (based on platelet count, absolute neutrophil count, hemoglobin level, or neutropenia with fever) may require dose reduction, delay in administration, or suspension of DOXIL® and/or VELCADE®
  - Persistent severe myelosuppression may result in superinfection, neutropenic fever, or hemorrhage
  - Sepsis occurring during neutropenia has resulted in discontinuation of treatment and, in rare cases, death
- DOXIL® may potentiate the toxicity of other anticancer therapies, especially hematologic toxicities, when used in combination with other therapies that suppress bone marrow
- Hand-foot syndrome (HFS) may occur during therapy with DOXIL®
  - Based on HFS toxicity grade, dose reduction, delay in administration, or discontinuation of DOXIL® may be required
  - HFS was generally observed after 2 to 3 cycles of treatment, but may occur earlier
    - The reaction was mild in most patients, resolving in 1 to 2 weeks
    - The reaction can be severe and debilitating in some patients, resulting in discontinuation of therapy
- DOXIL® is an irritant, not a vesicant; use precautions to avoid extravasation
- DOXIL® can cause fetal harm when used during pregnancy
- Recall reaction has occurred with DOXIL® administration after radiotherapy
- DOXIL® may interact with drugs known to interact with the conventional formulation of doxorubicin HCl
- In patients with recurrent ovarian cancer, the most common all-grade adverse reactions (ARs) ≥20% (DOXIL® vs topotecan, respectively) included: asthenia (40% vs 51%), fever (21% vs 31%), nausea (46% vs 63%), stomatitis (41% vs 15%), vomiting (33% vs 44%), diarrhea (21% vs 35%), anorexia (20% vs 22%), dyspnea (15% vs 23%), HFS (51% vs 1%), and rash (29% vs 12%)
  - In addition, 19% vs 52.3% reported alopecia (all grades)
  - Grade 3/4 hematologic ARs reported in ≥5% (DOXIL® vs topotecan, respectively) were neutropenia (12% vs 76%) and anemia (6% vs 29%)
- In patients with multiple myeloma, the most common all-grade ARs ≥20% (DOXIL® plus VELCADE® vs VELCADE®, respectively) included: neutropenia (36% vs 22%), thrombocytopenia (33% vs 28%), anemia (25% vs 21%), fatigue (36% vs 28%), pyrexia (31% vs 22%), asthenia (22% vs 18%), nausea (48% vs 40%), diarrhea (46% vs 39%), vomiting (32% vs 22%), constipation (31% vs 31%), mucositis/stomatitis (20% vs 5%), peripheral neuropathy (42% vs 45%), neuralgia (17% vs 20%), and rash (22% vs 18%)
  - In addition, 19% vs <1% reported HFS

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