CMS Manual System

Pub. 100-20 One-Time Special Notification

Department of Health & Human Services (DHHS) Centers for Medicare & Medicaid Services (CMS)

Transmittal 1 Date: SEPTEMBER 8, 2003

CHANGE REQUEST 2914

I. SUMMARY OF CHANGES: This notification indicates the method by which tositumomab and Iodine I-131 tositumomab (Bexxar) are paid if covered by the Medicare program.

NEW/REVISED MATERIAL - EFFECTIVE DATE: July 1, 2003
*IMPLEMENTATION DATE: October 1, 2003

Disclaimer: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged.

II. SCHEDULE OF CHANGES (R = REVISED, N = NEW, D = DELETED)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE	

III. FUNDING: *Medicare contractors only:

These instructions should be implemented within your current operating budget.

IV. ATTACHMENTS:

	Business Requirements	
	Manual Instruction	
	Confidential Requirements	
X	One-Time Notification	

One-Time Notification

SUBJECT:

I. GENERAL INFORMATION

A. Background: This notification indicates the method by which tositumomab and Iodine I-131 tositumomab (Bexxar) are paid if covered by the Medicare program. The Bexxar therapeutic regimen is administered in two separate steps: the dosimetric and the therapeutic. Each step consists of a sequential infusion of tositumomab followed by Iodine I-131 tositumomab.

The dosimetric step involves radionuclide scanning to determine the biodistribution of tositumomab. The procedure encompasses administration of non-radiolabeled tositumomab and whole body radionuclide scanning following administration of Iodine I-131 tositumomab. The purpose of the dosimetric dose is to determine individual pharmacokinetics and the amount of radioactivity to be delivered in the therapeutic dose. Determining appropriate biodistribution involves making a qualitative comparison of isotope uptake in several organ systems between three scans taken over the 7 days following the dosimetric administration of Iodine I-131 tositumomab. The therapeutic step is administered 7-14 days after the dosimetric step.

These instructions do not represent a determination that the Medicare program covers to situmomab or Iodine I-131 to situmomab. Contractors must determine whether the regimen meets all program requirements for coverage, for example, that it is reasonable and necessary to treat the beneficiary's condition, and whether it is excluded from payment because it is usually self-administered.

B. Policy:

Intermediaries:

- 1. When Bexxar is furnished to beneficiaries in a hospital outpatient department that is paid under the hospital outpatient prospective payment system (OPPS), hospitals are to bill using the following HCPCS codes:
 - a. **G3001**, **Administration and supply of tositumomab, 450mg** to bill for the infusion of tositumomab during the dosimetric/diagnostic step and to bill for the infusion of tositumomab during the therapeutic step.
 - b. G0273, Radiopharmaceutical biodistribution, single or multiple scans on one or more days, pre-treatment planning for radiopharmaceutical therapy of non-Hodgkin's lymphoma, includes administration of radiopharmaceutical (e.g., radiolabeled antibodies) for the Bexxar dosimetric dose using Iodine I-131 tositumomab. Note that G0273 includes all

- scans taken during the dosimetric step. G0273 should be billed only once, no matter how many scans are performed.
- c. G0274, Radiopharmaceutical therapy, non-Hodgkin's lymphoma, includes administration of radiopharmaceutical (e.g., radiolabeled antibodies) for the Bexxar therapeutic dose using Iodine I-131 tositumomab.
- d. **CPT 77300** to bill for dosimetry calculation.

NOTE: G3001 is a new code established effective July 1, 2003.

- 2. When Bexxar is furnished to beneficiaries in a hospital outpatient department that is paid under the OPPS, hospitals shall **NOT** bill using the following codes:
 - a. CPT codes for diagnostic administration of radiopharmaceuticals (78990 and 78999) or diagnostic scanning (78800 –78803).
 - b. CPT codes for therapeutic administration of radiopharmaceuticals (79900), radiopharmaceutical therapy (79100, 79400), or infusion or instillation of radioelement solution (77750).
- 3. Critical access hospitals and other hospital outpatient departments not paid under OPPS are to continue to utilize their current billing practices.
- 4. The OPPS payment for HCPCS codes G0273 includes payment for all scans.
- 5. The OPPS payment for G3001, G0273, and G0274 includes payment for both the radiopharmaceutical and administration of the radiopharmaceutical.
- 6. In situations where hospitals may have already submitted a claim using codes other than 77300, G3001, G0273 and G0274 to bill for Bexxar for services furnished on or after July 1, 2003 but before January 1, 2004, advise them that may submit an adjustment claim to receive payment for 77300, G3001, G0273 and G0274.
- C. **Provider Education:** Intermediaries shall inform affected providers by posting either a summary or relevant portions of this document on the website within two weeks. Also, intermediaries shall publish this same information in their next regularly scheduled bulletin. If they have a listsery that targets affected providers, they shall use it to notify subscribers that information about billing for tositumomab and Iodine I-131 tositumomab (Bexxar) is available on their website.

II. BUSINESS REQUIREMENTS

"Shall" denotes a mandatory requirement

"Should" denotes an optional requirement

Requirement #	Requirements	Responsibility
1.0	Intermediaries shall pay for G3001 under APC 9129 for	Intermediaries

	hospitals that are subject to OPPS and under current	
	payment methodologies for hospitals not subject to OPPS.	
1.1	Intermediaries shall advise their hospitals that may have already submitted a claim reflecting codes other than 77300, G3001, G0273 and G0274 to bill for Bexxar for services furnished on or after July 1, 2003 but before January 1, 2004 to submit an adjustment claim to receive	Intermediaries
2.0	payment for 77300, G3001, G0273 and G0274. Contractors shall inform affected providers by posting either a summary or relevant portions of this document on the website within two weeks. Also, contractors shall publish this same information in their next regularly scheduled bulletin. If they have a listserv that targets affected providers, they shall use it to notify subscribers that information about billing for tositumomab and Iodine I-131 tositumomab (Bexxar) is available on their website.	Intermediaries

III. SUPPORTING INFORMATION & POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions:

X-Ref Requirement #	Instructions
N/A	N/A

B. Design Considerations:

X-Ref Requirement #	Recommendation for Medicare System Requirements
N/A	No standard systems changes are to be made at this time.

C. Interfaces: N/A

D. Contractor Financial Reporting /Workload Impact: N/A

E. Dependencies: N/A

F. Testing Considerations: N/A

IV. SCHEDULE, CONTACTS, AND FUNDING

Effective Date: July 1, 2003	These instructions should be
Implementation Date: October 1, 2003	implemented within your current operating budget.
Pre-Implementation Contact(s): Division of Outpatient Care 410-786-0378	
Post-Implementation Contact(s): Division of Outpatient Care 410-786-0378	