Ibritumomab tiuxetan (Zevalin)

Policy Number: MM.04.013
Original Effective Date: 03/11/2003
Line(s) of Business: HMO; PPO
Current Effective Date: 06/22/2012
Section: Prescription Drugs
Place(s) of Service: Outpatient

I. Description

Ibritumomab tiuxetan (Zevalin) is a CD20-directed radiotherapeutic antibody administered as part of the ibritumomab tiuxetan therapeutic regimen indicated for the treatment of patients with relapsed or refractory, low-grade or follicular B-cell non-Hodgkin’s lymphoma (NHL) and for the treatment of patients with previously untreated follicular NHL who have achieved a partial or complete response to first-line chemotherapy.

Ibritumomab tiuxetan is comprised of two separate components, indium-111(IN-111) the diagnostic component and yttrium-90 (Y-90) the therapeutic component. The ibritumomab tiuxetan regimen includes the administration of rituximab followed by IN-111, which targets and binds to the tumor cell. If the IN-111 binds successfully to the tumor cells, seven to nine days later, a second dose of rituximab is administered followed by Y-90 which damages the targeted tumor cells.

II. Criteria/Guidelines

A. The ibritumomab tiuxetan therapeutic regimen is covered (subject to Limitations/Exclusions and Administrative Guidelines) when recommended by an oncologist for the following conditions:

1. Non-Hodgkin’s lymphoma (NHL)
   a. For the treatment of patients with relapsed or refractory, low-grade or follicular B-cell NHL
   b. For the treatment of patients with follicular NHL who achieve a partial or complete response to first-line chemotherapy

2. For the indications listed above, the following criteria must be met:
   a. Lymphoma involvement of the bone is less than 25 percent
b. Platelet count is greater than or equal to 100,000 cells/cubic millimeter

c. Neutrophil count is greater than or equal to 1,500 cells/cubic millimeter

d. Prior external beam radiation therapy not to exceed 25 percent of the bone marrow

e. No prior history of myeloablative therapy/autologous bone marrow transplant

B. Relapsed is defined as the reappearance of disease in the region of prior disease (recurrence) and/or in new regions (extensions) after initial therapy and attainment of complete response. Refractory is defined as no longer responding to therapy.

C. For all indications, HMSA follows NCCN level 1 or 2A and/or DrugDex level I or IIa recommendations

III. Limitations/Exclusions

The ibritumomab tiuxetan therapeutic regimen is intended as a single course of treatment. The safety and toxicity of multiple courses of the ibritumomab tiuxetan therapeutic regimen or of other forms of therapeutic irradiation preceding, following, or in combination with this therapeutic regimen have not been established.

IV. Administrative Guidelines

A. Precertification is required. To precertify, complete HMSA's Drug Review Request and mail or fax the form as indicated. Include the following documentation.

1. Clinical notes including any previous treatments.
2. Oncology notes
3. Pathology reports
4. Imaging studies

B. Applicable HCPCS/CPT codes:

### Diagnostic Services:

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>A9542</td>
<td>Indium In-111 ibritumomab tiuxetan, diagnostic, per study dose, up to 5 mCi</td>
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<tr>
<th>CPT Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>79403</td>
<td>Radiopharmaceutical therapy, radio-labeled monoclonal antibody by intravenous infusion</td>
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### Therapeutic Services:

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<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>A9543</td>
<td>Yttrium Y-90 ibritumomab tiuxetan, therapeutic, per treatment dose, up to 40 mCi</td>
</tr>
</tbody>
</table>
V. Important Reminder

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes § 432E-1.4), generally accepted standards of medical practice, and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA’s determination as to medical necessity in a given case, the physician may request that HMSA reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

VI. References