Zevalin® (ibritumomab tiuxetan)

Policy Number:	**M20200508037**
Effective Date:	**7/1/2020**
Sponsoring Department:	**Health Care Services**
Impacted Department(s):	**Health Care Services**

Type of Policy: ☒ Internal ☒ External

Data Classification: ☐Confidential ☐Restricted ☒Public

Applies to (Line of Business):

☐ Corporate (All)
☒ State Products, if yes which plan(s): ☒MediSource; ☒MediSource Connect; ☐Child Health Plus; ☒Essential Plan
☒ Medicare, if yes, which plan(s): ☒MAPD; ☐PDP; ☒ISNP; ☒CSNP
☒ Commercial, if yes, which type: ☒Large Group; ☒Small Group; ☒Individual
☒ Self-Funded Services *(Refer to specific Summary Plan Descriptions (SPDs) to determine any pre-authorization or pre-certification requirements and coverage limitations. In the event of any conflict between this policy and the SPD of a Self-Funded Plan, the SPD shall supersede the policy.)*

Excluded Products within the Selected Lines of Business (LOB)

N/A

Applicable to Vendors? Yes ☐ No☒

Purpose and Applicability:

To set forth Independent Health's criteria for **Zevalin® (ibritumomab tiuxetan)** for **non-Hodgkin's lymphoma (NHL).**

Policy:

Commercial, Self-Funded, Medicare Advantage:
Initial Criteria:

- Patient is 18 years or older; AND
- Patient must not have a platelet count < 100,000 cells/mm3; AND
- Must be used in combination with rituximab; AND
- Patient has adequate marrow cellularity of >15%; AND
- Patient has <25% involvement of lymphoma in bone marrow; AND

Coverage is provided in the following conditions:

1. Relapsed, refractory or progressive, low-grade or follicular non-Hodgkin's lymphoma (NHL)
    - Ibritumomab was not previously given

2. Previously Untreated Follicular NHL
    - Patient achieved a partial or complete response to first-line chemotherapy.

3. Diffuse Large B-cell Lymphoma (DLBCL)
    - Used as second-line or subsequent therapy for relapsed or refractory primary cutaneous disease of the leg type; OR
    - Used as subsequent therapy in patients who have had histologic transformation from marginal zone lymphoma or follicular lymphoma; AND
        - Patient experienced either a partial or no response or had progressive disease to treatment and received minimal or no treatment prior to histologic transformation (follicular lymphoma without translocations of MYC and BCL2 and/or BCL6); OR
        - Patient received multiple prior therapies including ≥2 lines of chemoimmunotherapy for indolent or transformed disease.

Dosage:

Administer rituximab 250 mg/m2 Day 1; repeat dose on Day 7, 8, or 9; Within 4 hours of the second dose of rituximab, administer ibritumomab as follows:

- Normal platelet counts:
  0.4 mCi/kg (14.8 MBq/kg) intravenously

- Relapsed/refractory patients with platelet count of 100,000 to 149,000 cells/mm3:
  0.3 mCi/kg (11.1 MBq/kg) intravenously

Do not exceed the maximum dose of 32.0 mCi (1184 MBq).

MediSource, MediSource Connect, Essential Plan:
MediSource, MediSource Connect, Essential Plan cover Zevalin utilizing the criteria above.

Background:
Non-Hodgkin lymphoma (NHL) consists of a diverse group of malignant neoplasms variously derived from B cell progenitors, T cell progenitors, mature B cells, mature T cells, or (rarely) natural killer cells. The clinical presentation of non-Hodgkin lymphoma (NHL) varies greatly depending on the type of lymphoma and the areas of involvement. Common presentations include lymphadenopathy, hepatosplenomegaly, fever, weight loss, and night sweats. Less common presentations include rash or side effects related to extranodal involvement. Follicular lymphoma (FL) is the second most common type of non-Hodgkin lymphoma (NHL). It is the most common of the clinically indolent NHLs defined as those lymphomas in which survival of the untreated patient is measured in years.

Radioimmunotherapy uses monoclonal antibodies linked to radioisotopes. Zevalin (Ibritumomab tiuxetan) is a murine anti-CD20 monoclonal antibody conjugated to the radioisotope yttrium-90 that is approved by the US Food and Drug Administration for the treatment of patients with relapsed or refractory FL, including patients with rituximab-refractory FL. Prospective trials of radioimmunotherapy demonstrate response rates of 60 to 80 percent in previously treated disease. Median progression free

survival is less than one year, but patients who achieve a complete remission have a median time to progression of close to four years.

An evaluation of the peer-reviewed scientific literature, including but not limited to subscription materials, has provided Independent Health the basis for its medical necessity coverage outlined above.

Pre-Authorization Required? Yes ☒ No ☐

Pre-authorization is required for this service.

Definitions

Non-Hodgkin's lymphoma (NHL) is a lymphoproliferative malignancy usually originating in lymphoid tissues and spreading to other organs. In general, with current treatment of patients with NHL, overall survival at 5 years is over 60%.

Zevalin® (ibritumomab tiuxetan) is a radiotherapeutic agent utilizing monoclonal antibodies labeled with a radioactive nuclide for the treatment of recurring or refractory CD20+ non-Hodgkin lymphoma (NHL).

References

Related Policies, Processes and Other Documents
N/A

Non-Regulatory references

Freedman AS, Friedman JW. Treatment of relapsed or refractory follicular lymphoma. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on April14, 2023.)

Freedman AS, Friedman JW, Asher JC. Clinical presentation and diagnosis of non-Hodgkin lymphoma. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on April 14, 2023.)

National Comprehensive Cancer Network (NCCN) [web site]. B-Cell Lymphomas Version 2.2023 – February 8, 2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf (Accessed April 14, 2023.)

Schaefer-Cutillo J, Friedberg JW, Fisher RI. Novel concepts in radioimmunotherapy for non-Hodgkin's lymphoma. Oncology (Williston Park). 2007 Feb;21(2):203-12;

Tennvall J, Fischer M, Bischof Delaloye A, et al.; Therapy Committee, EANM; Oncology Committee, EANM; Dosimetry Committee, EANM. EANM procedure guideline for radio-immunotherapy for B-cell lymphoma with 90Y-radiolabelled ibritumomab tiuxetan (Zevalin). Eur J Nucl Med Mol Imaging. 2007 Apr;34(4):616-22.

Witzig TE, Molina A, Gordon LI, et al. Long-term responses in patients with recurring or refractory B-cell non-Hodgkin lymphoma treated with yttrium 90 ibritumomab tiuxetan. Cancer. 2007 May 1;109(9):1804-10.

Regulatory References

Centers for Medicare and Medicaid (CMS) [web site]. Medicare Benefit Policy Manual Chapter 15 – Covered Medical and Other Health Services. Section 50.4.5. Available at: https://www.cms.gov/media/125221 Accessed April 14, 2023

New York State Department of Health [web site]. New York State Medicaid Program Physician Procedure Codes. Section 4 - Radiology. Version 2021. Available at: https://www.emedny.org/ProviderManuals/Physician/PDFS/Physician%20Procedure%20Codes%20Sect4.pdf Accessed April 14, 2023

United States Food and Drug Administration (FDA) [web site]. Zevalin (ibritumomab tiuxetan) Label. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/125019s0156.pdf Accessed April 14, 2023

This policy contains medical necessity criteria that apply for this service. Please note that payment for covered services is subject to eligibility criteria, contract exclusions and the limitations noted in the member's contract at the time the services are rendered.

Version Control

Signature / Approval on File? Yes ☒ No☐

Revision Date	Owner	Notes
1/1/2024	Health Care Services	Revised
6/1/2023	Health Care Services	Reviewed
6/1/2022	Health Care Services	Reviewed
6/1/2021	Health Care Services	Reviewed