Drug Policy:
Treanda/Bendeka/Belrapzo™ (bendamustine)

I. PURPOSE
To define and describe the accepted indications for Treanda/Bendeka/Belrapzo (bendamustine) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century Health (NCH) is responsible for processing all medication requests from network ordering providers. Medications not authorized by NCH may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

A. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:
   1. When health plan Medicaid coverage provisions—including any applicable PDLs (Preferred Drug Lists)—conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the Preferred Drug Guidelines OR
2. When health plan Exchange coverage provisions—including any applicable PDLs (Preferred Drug Lists)—conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the Preferred Drug Guidelines OR

3. For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the Preferred Drug Guidelines shall follow NCH L1 Pathways when applicable, otherwise shall follow NCH drug policies AND

4. Continuation requests of previously approved, non-preferred medication are not subject to this provision AND

5. When available, generic alternatives are preferred over brand-name drugs.

B. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma
   1. Note: Unless there is prior history of hypersensitivity reactions or intolerance, the preferred bendamustine product is Bendeka over Belrapzo or Treanda for all indications and line of therapy.
   2. In combination with Rituxan (rituximab) for initial or subsequent therapy for members with CLL.

C. Non-Hodgkin’s Lymphoma
   1. Note: Unless there is prior history of hypersensitivity reactions or intolerance, the preferred bendamustine product is Bendeka over Belrapzo or Treanda for all indications and line of therapy.
   2. Indolent B-Cell Lymphomas
      a. In combination with Rituxan (rituximab) for primary or subsequent therapy of any of the following:
         i. Follicular B-Cell Lymphoma
         ii. Nodal Marginal Zone/Extra-Nodal Marginal Zone/Gastric MALT Lymphoma/Non-Gastric MALT Lymphoma/Splenic Marginal Zone Lymphoma.
   3. Diffuse Large B-Cell Lymphoma
      a. Second-line therapy for relapsed or refractory disease.
   4. Mantle Cell Lymphoma
      a. Initial or subsequent therapy in combination with Rituxan (rituximab).

III. EXCLUSION CRITERIA
   A. Member has disease progression while on Treanda/Bendeka/Belrapzo (bendamustine).
   B. Dosing exceeds single dose limit of Treanda/Bendeka/Belrapzo (bendamustine) 120 mg/m².
   C. Treatment with Treanda/Bendeka/Belrapzo (bendamustine) exceeds the maximum duration limit of 8 cycles for NHL and 6 cycles for CLL.
   D. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

IV. MEDICATION MANAGEMENT
   A. Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY
   A. Review – Utilization Management Department
B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES