Drug Policy:
Monjuvi™ (tafasitamab-cxix)

I. PURPOSE
To define and describe the accepted indications for Monjuvi (tafasitamab-cxix) 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. Diffuse Large B Cell Lymphoma (DLBCL)

NOTE: Per NCH Policy & NCH Pathway, this is a non-preferred agent for relapsed/refractory DLBCL. Please refer to the NCH pathway document for the preferred regimens in relapsed/refractory DLBCL.

1. The member has relapsed/refractory DLBCL AND
2. Is ineligible for autologous or allogeneic hematopoietic stem cell transplant AND
3. Has received a chemoimmunotherapy regimen that included a CD20-targeted therapy (e.g. rituximab, ofatumumab, obinutuzumab) AND
4. Has had an inadequate response to 2 or more salvage chemoimmunotherapy regimens in the relapsed/refractory setting (e.g. R-ICE, R-DHAP, R-ESHAP, R-EPOCH, or R-GDP) AND
5. Monjuvi (tafasitamab-cxix) will be used in combination with lenalidomide up to 12 cycles.

III. EXCLUSION CRITERIA

A. Monjuvi (tafasitamab-cxix) is being used on or after disease progression with the same regimen.
B. Dosing exceeds single dose limit of Monjuvi (tafasitamab-cxix) 12 mg/kg.
C. Treatment exceeds the maximum months duration limit of 12 cycles (when used in combination with lenalidomide).
D. Indications not supported by CMS-recognized compendia or acceptable peer-reviewed literature.

IV. MEDICATION MANAGEMENT

A. Grade 3 or 4 febrile neutropenia is 6% (low risk level).^
B. The frequency of emesis is 15% (low risk level).^
C. 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

D. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics
F. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer