Drug Policy:

Imjudo™ (tremelimumab)

POLICY NUMBER UM ONC_1469	**SUBJECT** Imjudo™ (tremelimumab)		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 3**
DATES COMMITTEE REVIEWED 12/14/22	**APPROVAL DATE** December 14, 2022	**EFFECTIVE DATE** December 30, 2022	**COMMITTEE APPROVAL DATES** 12/14/22	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
URAC STANDARDS HUM v8: UM 1-2; UM 2-1	**NCQA STANDARDS** UM 2		**ADDITIONAL AREAS OF IMPACT**	
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid	

I. PURPOSE

To define and describe the accepted indications for Imjudo (tremelimumab) 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. When Health Plans utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, and there is no Health Plan PDL applicable, the Preferred Drug Guidelines shall follow NCH recommended agents/regimens/preferred drugs AND
4. Continuation requests of previously approved, non-preferred medication are not subject to this provision AND
5. When applicable, generic alternatives are preferred over brand-name drugs AND
6. When there is a documented drug shortage, disease progression, contraindication, or confirmed intolerance to a preferred drug/regimen, per NCH Policy and Pathway, the available alternative product may be used if deemed medically appropriate and the indication is listed in a standard reference compendia or accepted peer review literature. For a list of current drug shortages, please refer to FDA drug shortage website in the reference section.

B. Hepatocellular Carcinoma

1. The member has unresectable hepatocellular carcinoma (Child-Pugh Class A score only) with no prior systemic treatment, including prior checkpoint inhibitor (e.g., dostarlimab-gxly, atezolizumab, nivolumab, pembrolizumab, ipilimumab) AND
2. Imjudo (tremelimumab) will be used (for one cycle) as first line therapy in combination with Imfinzi (durvalumab) followed by continuation of Imfinzi (durvalumab).

C. Non-Small Cell Lung Cancer (NSCLC)

1. The member has not received prior systemic therapy for recurrent/metastatic or Stage IV NSCLC and the tumor is negative for EGFR and ALK, regardless of PD-L1 expression AND
2. Imjudo (tremelimumab) will be used as first line therapy in combination with Imfinzi (durvalumab) and platinum-based chemotherapy [maximum of 5 doses of Imjudo (tremelimumab)].

III. EXCLUSION CRITERIA

A. Disease progression while taking Imjudo (tremelimumab) or prior checkpoint inhibitor (e.g., dostarlimab-gxly, atezolizumab, nivolumab, pembrolizumab, ipilimumab).

B. For Hepatocelluar Carcinoma: Dosing exceeds single dose limit of Imjudo (tremelimumab) 300 mg (for weight greater than or equal to 30 kg) or 4 mg/kg (for weight less than 30 kg). Treatment exceeds one time dose administration of Imjudo (tremelimumab).

C. For NSCLC: Dosing exceeds single dose limit of Imjudo (tremelimumab) 75 mg/kg (for weight 30 kg or more) or 1 mg/kg (for weight less than 30 kg). Treatment exceeds 5 doses/5 cycles of Imjudo (tremelimumab).

D. Investigational use of Imjudo (tremelimumab) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:

1. Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
2. Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
3. Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definition of Clinically Meaningful outcomes are those

recommended by ASCO, e.g., Hazard Ratio of less than 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.

4. Whether the experimental design, in light of the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
5. That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
6. That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
7. That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

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

A. Johnson ML, et al. POSEIDON Clinical Trial. Durvalumab With or Without Tremelimumab in Combination With Chemotherapy as First-Line Therapy for Metastatic Non-Small-Cell Lung Cancer: The Phase III POSEIDON Study. J Clin Oncol. 2022 Nov 3:JCO2200975.

B. Abou-Alfa et alHIMALAYA Clinical Trial. Durvalumab plus tremelimumab in unresectable hepatocellular carcinoma. June 6, 2022. NEJM Evid 2022;1(8). DOI: https://doi.org/10.1056/EVIDoa2100070

C. Imjudo prescribing information. AstraZeneca Pharmaceuticals LP 2022. Wilmington, DE 2022.

D. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs Bethesda, MD 2022.

E. Clinical Pharmacology Elsevier Gold Standard 2022.

F. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, CO 2022.

G. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2022.

H. Ellis LM, et al. American Society of Clinical Oncology perspective: Raising the bar for clinical trials by defining clinically meaningful outcomes. J Clin Oncol. 2014 Apr 20;32(12):1277-80.

I. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.

J. NCQA UM 2022 Standards and Elements.