Alpha-Fetoprotein

MEDICAL POLICY NUMBER: 406

Effective Date: 6/1/2024

Last Review Date: 5/2024

Next Annual Review: 5/2025

COVERAGE CRITERIA 2
POLICY CROSS REFERENCES 2
POLICY GUIDELINES 2
REGULATORY STATUS 3
BILLING GUIDELINES AND CODING 3
REFERENCES 4
POLICY REVISION HISTORY 4

INSTRUCTIONS FOR USE: Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

SCOPE: Providence Health Plan, Providence Health Assurance and Providence Plan Partners as applicable (referred to individually as “Company” and collectively as “Companies”).

PLAN PRODUCT AND BENEFIT APPLICATION

☒ **Commercial** ☐ **Medicaid/OHP*** ☐ **Medicare****

*Medicaid/OHP Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

Alpha-Fetoprotein – Guideline Note 173

**Medicare Members

This *Company* policy may be applied to Medicare Plan members only when directed by a separate *Medicare* policy. Note that investigational services are considered **"not medically necessary"** for Medicare members.

COVERAGE CRITERIA

I. Alpha-fetoprotein testing may be considered **medically necessary** in the following situations:

   A. For the diagnosis of hepatocellular carcinoma in high-risk patients
   B. Separating patients with benign hepatocellular neoplasms or metastases from those with hepatocellular carcinoma
   C. As a non-specific tumor associated antigen, serving in marking germ cell neoplasms of the testis, ovary, retroperitoneum, and mediastinum.

Link to Evidence Summary

POLICY CROSS REFERENCES

None

The full Company portfolio of current Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

This policy may be primarily based on the following Center for Medicare and Medicaid Services (CMS) guidance resources:

- National Coverage Determination (NCD): Alpha-fetoprotein (190.25)[1]

BACKGROUND

Alpha-fetoprotein (AFP): AFP is a polysaccharide found in some carcinomas. It is effective as a biochemical marker for monitoring the response of certain malignancies to therapy.

REGULATORY STATUS

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. Therefore, this section is provided for informational purposes only.

BILLING GUIDELINES AND CODING

The CPT/HCPCS codes may be covered when billed with one of the ICD-10 codes included in the most recent "Medicare National Coverage Determinations (NCD) Coding Policy Manual and Change Report (ICD-10-CM)," available for download at "Lab NCDs – ICD-10."[2] Please see the coding policy manual for a complete list of diagnosis codes.

This policy does not address AFP testing of amniotic fluid (CPT 82106).

CODES*		
CPT	82105	Alpha-fetoprotein (AFP); serum
HCPCS	None	

***Coding Notes:**

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

REFERENCES

1. Centers for Medicare & Medicaid Services. Alpha-fetoprotein. 190.25. Effective 11/25/2002. https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=121. Accessed 4/101/2024.
2. Centers for Medicare & Medicaid Services. Lab NCDs - ICD-10. https://www.cms.gov/Medicare/Coverage/CoverageGenInfo/LabNCDsICD10. Published 2024. Accessed 4/10/2024.

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
6/2024	New medical policy.