Medicare Medical Policy

Apheresis (Therapeutic Pheresis)

MEDICARE MEDICAL POLICY NUMBER: 310

Effective Date: 9/1/2024

Last Review Date: 8/2024

Next Annual Review: 8/2025

INSTRUCTIONS FOR USE: Company Medicare Medical Policies serve as guidance for the administration of plan benefits and do not constitute medical advice nor a guarantee of coverage. Company Medicare Medical Policies are reviewed annually to guide the coverage or non-coverage decision-making process for services or procedures in accordance with member benefit contracts (otherwise known as Evidence of Coverage or EOCs) and Centers of Medicare and Medicaid Services (CMS) policies, manuals, and other CMS rules and regulations. In the absence of a CMS coverage determination or specific regulation for a requested service, item or procedure, Company policy criteria or applicable utilization management vendor criteria may be applied. These are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. 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.

The Company reserves the right to determine the application of Medicare Medical Policies and make revisions to these policies at any time. Any conflict or variance between the EOC and Company Medical Policy will be resolved in favor of the EOC.

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

PRODUCT AND BENEFIT APPLICATION

☒ Medicare Only

MEDICARE COVERAGE CRITERIA

IMPORTANT NOTE: More than one Centers for Medicare and Medicaid Services (CMS) reference may apply to the same health care service, such as when more than one coverage policy is available (e.g., both an NCD and LCD exist). All references listed should be considered for coverage decision-making. The Company uses the most current version of a Medicare reference available at the time of publication; however, these websites are not maintained by the Company, so Medicare references and their corresponding hyperlinks may change at any time. If there is a conflict between the Company Medicare Medical Policy and CMS guidance, the CMS guidance will govern.

Service	Medicare Guidelines
Apheresis (Therapeutic Pheresis) for Familial Hypercholesterolemia (CPT 36516)	Local Coverage Article (LCA): Therapeutic Apheresis for Familial Hypercholesterolemia (A54543)
Apheresis (Therapeutic Pheresis) for Other Indications (36511-36516)	National Coverage Determination (NCD): Apheresis (Therapeutic Pheresis) (110.14) **NOTE:** Neither the above NCD nor LCA indicate selective high-density lipoprotein (HDL) delipidation and apheresis is a covered procedure. Therefore, Company medical policy criteria will apply (see below).
Extracorporeal photopheresis (CPT 36522)	NCD: Extracorporeal Photopheresis (110.4) **NOTE:** Medicare coverage of extracorporeal photopheresis used for the treatment of bronchiolitis obliterans syndrome (BOS) following lung allograft transplant requires the extracorporeal photopheresis to be provided under an approved clinical research study. As of the date of policy development, there is only one Medicare approved study, which can be found on the Medicare website.
Medicare Coverage Criteria: "MA organizations may create publicly accessible internal coverage criteria… when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs." *(§ 422.101(b)(6) – see Policy Guidelines below*) • **Medicare Coverage Manuals:** Medicare does not have criteria for apheresis in a coverage manual, for any indication. • **National Coverage Determination (NCD):** With the exception of services noted above addressed by an NCD, there are no NCDs for apheresis for any other indication. This NCD is considered "not fully established" under CFR § 422.101(6)(i)(C) as there are no Medicare	

coverage policies to address selective high-density lipoprotein (HDL) delipidation and apheresis (0342T). • **Noridian J-F Local Coverage Determination (LCD)/Local Coverage Article (LCA):** As of the most recent policy review, no Medicare Administrative Contractors (MACs) have LCDs for 0342T. • Therefore, in the absence of established Medicare coverage criteria in a manual, NCD, LCD, or other regulatory guidance for the health plan's service area, Company criteria below are applied for medical necessity decision-making.	
Selective high-density lipoprotein (HDL) delipidation and apheresis (CPT 0342T)	Company medical policy for Apheresis (Therapeutic Pheresis) I. This service is considered **not medically necessary** for Medicare based on the Company medical policy. *See Policy Guidelines below.*

IMPORTANT NOTICE: While some services or items may appear medically indicated for an individual, they may also be a direct exclusion of Medicare or the member's benefit plan. Such excluded services or items by Medicare and member EOCs include, but are not limited to, services or procedures considered to be cosmetic, not medical in nature, or those considered not medically reasonable or necessary under *Title XVIII of the Social Security Act, §1862(a)(1)(A).* If there is uncertainty regarding coverage of a service or item, please review the member EOC or submit a pre-service organization determination request. Note that the Medicare Advance Beneficiary Notice of Noncoverage (ABN) form **cannot** be used for Medicare Advantage members. *(Medicare Advance Written Notices of Non-coverage. MLN006266 May 2021)*

POLICY CROSS REFERENCES

None

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

POLICY GUIDELINES

MEDICARE AND MEDICAL NECESSITY

Only medically reasonable and necessary services or items which treat illness or injury are eligible for Medicare coverage, as outlined in *Title XVIII of the Social Security Act, §1862(a)(1)(A)*. MA organizations (MAOs) make medical necessity determinations based on coverage and benefit criteria, current standards of care, the member's unique personal medical history (e.g., diagnoses, conditions, functional status, co-morbidities, etc.), physician recommendations, and clinical notes, as well as involvement of a plan medical director, where appropriate. *(§ 422.101(c)(1))*

In addition:

> "MA organizations may create publicly accessible internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs. Current, widely-used treatment guidelines are those developed by organizations representing clinical medical specialties, and refers to guidelines for the treatment of specific diseases or

conditions. Acceptable clinical literature includes large, randomized controlled trials or prospective cohort studies with clear results, published in a peer-reviewed journal, and specifically designed to answer the relevant clinical question, or large systematic reviews or meta-analyses summarizing the literature of the specific clinical question." *(§ 422.101(b)(6) and Medicare Managed Care Manual, Ch. 4, §90.5)*

The Company policy for *PHA Medicare Medical Policy Development and Application* (MP50) provides details regarding Medicare's definition of medical necessity and the hierarchy of Medicare references and resources during the development of medical policies, as well as the Plan's use of evidence-based processes for policy development.

Historically, the now-retired Noridian LCD for *Non-Covered Services* (L35008) considered all Category III codes to be non-covered, "unless specifically approved for payment by CMS or the Noridian Medical Directors and listed as approved" in the separate local coverage article (LCA) for *Additional Information Required for Coverage and Pricing for Category III CPT® Codes* (A55681).

Category III code 0342T, used to report "therapeutic apheresis with selective HDL delipidation and plasma reinfusion" **was** included in LCA A55681 as a "Group 1" code since July 2017, as well as the LCA for *Billing and Coding: Non-Covered Services* (A57642), indicating this was a service which Noridian considered **non-covered** for several years. While the LCD L35008 and LCAs A57642 and A55681 were all retired in June 2020 to "align with Chapter 13 of the Program Integrity Manual (PIM)," this retirement does not mean these services became medically necessary, it only means the Medicare contractor did not choose to develop or maintain a new LCD/LCA for this service.

Since there are not fully established coverage criteria for selective HDL delipidation and apheresis (CPT 0342T) available in applicable Medicare statutes, regulations, NCDs or LCDs, then Company medical policy criteria for code 0342T will be applied. See the Medicare Coverage Criteria table above for more information regarding the use of internal coverage criteria when Medicare coverage criteria are not fully established.

REGULATORY STATUS

U.S. FOOD & DRUG ADMINISTRATION (FDA)

While clearance by the Food and Drug Administration (FDA) is a prerequisite for Medicare coverage, the 510(k) premarket clearance process does not in itself establish medical necessity. Medicare payment policy is determined by the interaction of numerous requirements, including but not limited to, the availability of a Medicare benefit category and other statutory requirements, coding and pricing guidelines, as well as national and local coverage determinations and clinical evidence.

BILLING GUIDELINES AND CODING

GENERAL

See the associated Medicare Claims Processing Manual, Chapter 4 - Medicare Claims Processing Manual, Chapter 4 - Part B Hospital (Including Inpatient Hospital Part B and OPPS), §231.9 - Billing for Pheresis and Apheresis Services for general billing guidance for therapeutic apheresis.

See the associated Medicare Claims Processing Manual, Chapter 32 – Billing Requirements for Special Services, §190 – Billing Requirements for Extracorporeal Photopheresis for general billing guidance for extracorporeal photopheresis.

CODES*		
CPT	0342T	Therapeutic apheresis with selective HDL delipidation and plasma reinfusion
	36511	Therapeutic apheresis; for white blood cells
	36512	Therapeutic apheresis; for red blood cells [red blood cell exchange]
	36513	Therapeutic apheresis; for platelets
	36514	Therapeutic apheresis; for plasma pheresis
	36516	Therapeutic apheresis; with extracorporeal immunoadsorption, selective adsorption or selective filtration and plasma reinfusion
	36522	Photopheresis, extracorporeal
HCPCS	None	

***Coding Notes:**

- The code list above 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. According to Medicare, "presence of a payment amount in the MPFS and the Medicare physician fee schedule database (MPFSDB) does not imply that CMS has determined that the service may be covered by Medicare." The issuance of a CPT or HCPCS code or the provision of a payment or fee amount by Medicare does **not** make a procedure medically reasonable or necessary or a covered benefit by Medicare. *(Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements, §30 - Services Paid Under the Medicare Physician's Fee Schedule, A. Physician's Services)*
- 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

None

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
11/2022	New Medicare Advantage medical policy (converted to new format 2/2023)

11/2023	Annual review, no criteria changes but language revision due to policy changes from "Investigational" to "not medically necessary"
9/2024	Annual review, no change to criteria