MEDICAL POLICY	Apheresis (Therapeutic Pheresis) (Medicare Only)
Effective Date: 11/1/2022  11/1/2022 Medical Officer Date	Medical Policy Number: 310 Medical Policy Committee Approved Date: 7/2021; 8/2022

See Policy CPT/HCPCS CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as "Company" and collectively as "Companies").

APPLIES TO:

Medicare Only

MEDICARE POLICY CRITERIA

The following Centers for Medicare & Medicaid Service (CMS) guidelines should be utilized for medical necessity coverage determinations. Click the link provided in the table below to access applicable medical necessity criteria. All listed guidelines apply.

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.
Selective high-density lipoprotein (HDL) delipidation and apheresis (CPT 0342T)	Company medical policy for Apheresis (Therapeutic Pheresis) (All Lines of Business Except Medicare) I. This service is considered **not medically necessary** for Medicare based on the Company medical policy. *Services deemed "investigational" are considered not medically necessary for Medicare Plan members. See Policy Guidelines below.*

POLICY GUIDELINES

Medicare and Medical Necessity

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. In the absence of Medicare coverage policies (e.g., manual, national coverage determination [NCD], local coverage determination [LCD], article [LCA], etc.), Medicare regulatory guidelines do allow Medicare Advantage Organizations (MAOs) to make their own coverage determinations, as long as the MAO applies an objective, evidence-based process, based on authoritative evidence. *(Medicare Managed Care Manual, Ch. 4, §90.5)*

Following an evidence-based assessment of current peer-reviewed medical literature, the Company may consider certain medical services or technologies to be "investigational." The term "investigational" is not limited to devices or technologies which have not received the appropriate governmental regulatory approval (e.g., U.S. Food and Drug Administration [FDA]), but rather may also mean the procedure, device, or technology does not meet all of the Company's technology assessment criteria, as detailed within the Company policy for *Definition: Experimental/Investigational* (MP5).

For Medicare, 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)*. Thus, services which lack scientific evidence regarding safety and efficacy because they are investigational are "not medically reasonable or necessary" for Medicare Plan members. *(Medicare Claims Processing Manual, Ch. 23, §30 A)*

BILLING GUIDELINES

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.

CPT/HCPCS CODES

Medicare Only	
Prior Authorization Required Note: The following codes do not require prior authorization when billed at location code 21 (inpatient hospital).	
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
Not Covered	
0342T	Therapeutic apheresis with selective HDL delipidation and plasma reinfusion

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 Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days notice of policy changes that are restrictive in nature.

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.

REGULATORY STATUS

Mental Health Parity Statement

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.