MEDICAL POLICY	Chelation Therapy for Non-Overload Conditions (Medicare Only)
Effective Date: 4/1/2022  4/1/2022 Medical Officer Date	Medical Policy Number: 518 Medical Policy Committee Approved Date: 2/2022

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.

Note: This policy is specific to chelation therapy for *non-overload* conditions. It does not address chelation therapy for *overload* conditions, which may be considered medically necessary and standard of care.

Service	Medicare Guidelines
Chelation Therapy as Treatment of Atherosclerosis, Arteriosclerosis or Calcinosis (aka, chemoendarterectomy or chemical endarterectomy) (HCPCS M0300)	• National Coverage Determination (NCD): Chelation Therapy for Treatment of Atherosclerosis (20.21) • NCD: Ethylenediamine-Tera-acetic (EDTA) Chelation Therapy for Treatment of Atherosclerosis (20.22)

In the absence of a Medicare coverage policy or guidance (e.g., manual, national coverage determination [NCD], local coverage determination [LCD], article [LCA], etc.), Medicare guidelines allow a Medicare Advantage Organization (MAO) to make coverage determinations, applying an objective, evidence-based process, based on authoritative evidence. (Medicare Managed Care Manual, Ch. 4, §90.5) Medicare coverage guidance is not available for the Company's service area

for chelation therapy as treatment for all other non-overload conditions. Therefore, the commercial medical policy, **Chelation Therapy for Non-Overload Conditions (All Lines of Business Except Medicare)** *applies.*

- Chelation therapy for treatment of **all other non-overload** conditions

BILLING GUIDELINES

HCPCS code G0068 does not require prior authorization or routine review for medical necessity, but may be subject to utilization audit.

The *National Physician Fee Schedule Relative Value File (NPFSRVF)*, which is published by Medicare[1], indicates HCPCS code M0300 has been assigned a Status Indicator of "N," which is defined as "Non-covered Services." This is a statutorily excluded service based on the NCDs noted above.

The following codes are not specific to chelation therapy, but may be billed in conjunction with M0300 or S9355.

• 96365-96368
• J0470
• J0600
• J0895
• J3520

Like all S-codes, the *NPFSRVF* indicates HCPCS code S9355 has been assigned a Status Indicator of "I." This is defined as "Not valid for Medicare purposes." HCPCS code S9355 is not covered unless allowed under a Medicare Advantage provider contract exception, as indicated in the relevant Company coding policy. In addition to provider contract exception requirements, **HCPCS code S9355 will only be covered if billed with one of the following diagnosis codes**:

- D56.1
- D57.00–D57.819
- D61.01
- E72.01
- E83.01
- E83.111
- E83.52
- K74.3
- K74.4
- K74.5
- T36-T65 with fifth or sixth character 1-4 or 6
- T45.4x1A - T45.4x5S
- T46.0x1A – T46.0x4S
- T47.1X5A –T47.1x5S
- T56.0x1A - T56.0x4S
- T56.1x1A - T56.1x4S
- T56.3x1A - T56.3x4S
- T56.4x1A - T56.4x4S
- T56.5x1A - T56.5x4S
- T56.811A - T56.814S
- T56.891A - T56.894.S
- T56.91xA - T56.94xS
- T57.0x1A - T57.0X4S
- T80.92xA - T80.92xS
- K71.XXX
- N14.3
- T57.2XX

CPT/HCPCS CODES

Medicare Only	
No Prior Authorization Required	
G0068	Professional services for the administration of anti-infective, pain management, chelation, pulmonary hypertension, inotropic, or other intravenous infusion drug or biological (excluding chemotherapy or other highly complex drug or biological) for each infusion drug administration calendar day in the individual's home, each 15 minutes
S9355	Home infusion therapy, chelation therapy; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem
Non-Covered	
M0300	IV chelation therapy (chemical endarterectomy)

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.

REFERENCES

1. Medicare Physician Fee Schedule (PFS) Relative Value Files; Available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Relative-Value-Files