


MEDICAL POLICY	Clinical Trials and IDE Studies (Medicare Only)
Effective Date: 9/1/2021  <div style="text-align: right;">9/1/2021</div>	Medical Policy Number: 233
	Medical Policy Committee approved Date: 11/09; 1/10; 4/12; 5/13; 10/14; 10/15; 9/16; 7/17; 12/18; 2/19; 3/2020; 08/2020; 8/2021
Medical Officer Date	

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

SCOPE:

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

APPLIES TO:

Medicare only

MEDICARE POLICY CRITERIA	
<p>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.</p>	
Service	Medicare Guidelines
<i>Routine costs in clinical trials</i>	<ul style="list-style-type: none"> Centers for Medicare & Medicaid Services National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1)¹ Medicare Claims Processing Manual, Chapter 32 – Billing Requirements for Special Services (search document for <i>clinical trials</i> as numerous sections may be relevant)²
<i>Food and Drug Administration (FDA)-Approved Investigational Device Exemption (IDE) Studies</i>	<ul style="list-style-type: none"> Medicare Benefit Policy Manual, Chapter 14 - Medical Devices³ Medicare Benefit Policy Manual, Chapter 4 – Benefits and Beneficiary Protections⁴ Medicare Claims Processing Manual, Chapter 32 – Billing Requirements for Special Services (search document for <i>clinical trials</i> as numerous sections may be relevant)²
<i>Clinical Studies Approved Under Coverage with Evidence Development (CED)</i>	<ul style="list-style-type: none"> Medicare Benefit Policy Manual, Chapter 4 – Benefits and Beneficiary Protections⁴ Medicare Claims Processing Manual, Chapter 32 – Billing Requirements for Special Services (search document for <i>clinical trials</i> as numerous sections may be relevant)²

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BILLING GUIDELINES

For additional billing guidance, see [MLN Matters® Number: MM6776](#).⁵

CPT/HCPCS CODES

All Lines of Business Except Medicare	
No Prior Authorization Required	
C9760	Non-randomized, non-blinded procedure for nyha class ii, iii, iv heart failure; transcatheter implantation of interatrial shunt or placebo control, including right and left heart catheterization, transeptal puncture, trans-esophageal echocardiography (tee)/intracardiac echocardiography (ice), and all imaging with or without guidance (e.g., ultrasound, fluoroscopy), performed in an approved investigational device exemption (ide) study

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

- Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1). Effective Date of this Version: 7/9/2007.

- <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=1&ncdver=2&DocID=310.1&bc=gAAAAAgAAAAAA%3d%3d&>. Accessed 7/21/2021.
2. Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual, Chapter 32 – Billing Requirements for Special Services. (Rev. 10796, 05-20-21), .
<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c32.pdf>. Accessed 7/21/2021.
 3. Centers for Medicare & Medicaid Services. Medicare Benefit Policy Manual, Chapter 14 - Medical Devices. (Rev. 198, Issued: 11-06-14, Effective: 01-01-15, Implementation: 01-05-15).
<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c14.pdf>. Accessed 7/21/2021.
 4. Centers for Medicare & Medicaid Services. Medicare Managed Care Manual, Chapter 4 - Benefits and Beneficiary Protections. (Rev. 121, Issued: 04-22-16, Implementation: 04-22-16).
<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf>. Accessed 7/21/2021.
 5. Centers for Medicare & Medicaid Services. MLN Matters® Number: MM6776 (Revised). Related CR Release Date: 09/17/2010. Related CR Transmittal #: R2052CP. Effective Date: 09/19/2000. Implementation Date: July 6, 2010. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2010-Transmittals-Items/CMS1239536>. Accessed 7/21/2021.