

<b>CMS Manual System</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Pub 100-03 Medicare National Coverage Determinations</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
<b>Transmittal 12112</b>	<b>Date: June 29, 2023</b>
	<b>Change Request 13220</b>

**SUBJECT: Technical Revisions Only to the National Coverage Determination (NCD) Manual, Publication (Pub) 100-03**

**I. SUMMARY OF CHANGES:** The purpose of this Change Request (CR) is to announce technical changes that were made to the National Coverage Determination (NCD) Manual, Publication 100-03, Chapter 1 Parts 1, 3, and 4. Proposed manual changes include: (1) In Chapter 1, Part 1, Section 20.33 Transcatheter Edge-To-Edge (TEER) for Mitral Valve Regurgitation title was corrected to align with the title of the NCD. (2) In Chapter 1, Part 1, Section 20.4 Implantable Cardioverter Defibrillators (ICDs), in Part B number 4 added verbiage ‘or cardiac arrest due to VF’ to align with Section I of the Final Decision Memo. (3) In Chapter 1, Part 3, Section 190.1 Histocompatibility Testing, removed 4 bullets and replaced them with letters to align with the original Coverage Issues Manual language. (4) In Chapter 1, Part 4, Section 280.1, in the DME reference list, the Muscle Stimulator hyperlink is being changed from 250.4 to 160.12 to refer back to the correct section in the manual.

**EFFECTIVE DATE: July 31, 2023**

*\*Unless otherwise specified, the effective date is the date of service.*

**IMPLEMENTATION DATE: July 31, 2023** *Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.*

**II. CHANGES IN MANUAL INSTRUCTIONS:** (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

<b>R/N/D</b>	<b>CHAPTER / SECTION / SUBSECTION / TITLE</b>
R	1/Part 1/20/20.33/Transcatheter Edge-to-Edge (TEER) for Mitral Valve Regurgitation
R	1/Part1/20/20.4/Implantable Cardioverter Defibrillators (ICDs)
R	1/Part 3/190/190.1/Histocompatibility Testing
R	1/Part 4/280/280.1/Durable Medical Equipment Reference List (Effective May 5, 2005)

**III. FUNDING:**

**For Medicare Administrative Contractors (MACs):**

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to

be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

#### **IV. ATTACHMENTS:**

**Business Requirements  
Manual Instruction**

# Attachment - Business Requirements

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**SUBJECT: Technical Revisions Only to the National Coverage Determination (NCD) Manual, Publication (Pub) 100-03**

**EFFECTIVE DATE: July 31, 2023**

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**IMPLEMENTATION DATE: July 31, 2023**

## I. GENERAL INFORMATION

**A. Background:** The purpose of this Change Request (CR) is to identify several technical changes to the Pub 100-03 manual. No policy is being changed as a result of these revisions.

**B. Policy:** No policy changes.

## II. BUSINESS REQUIREMENTS TABLE

*"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.*

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
13220.1	Contractors shall be aware of the technical revisions to the NCD Manual as noted above. No policy is affected by these revisions.	X	X		X					

## III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
13220.2	CR as Provider Education: Contractors shall post this entire instruction, or a direct link to this instruction, on their Web sites and include information about it in a listserv message within 5 business days after receipt of the notification from CMS announcing the availability of the article. In addition, the entire instruction must be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement it with localized information that would benefit	X	X		X	

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
	their provider community in billing and administering the Medicare program correctly.					

**IV. SUPPORTING INFORMATION**

**Section A: Recommendations and supporting information associated with listed requirements: N/A**

*"Should" denotes a recommendation.*

X-Ref Requirement Number	Recommendations or other supporting information:

**Section B: All other recommendations and supporting information: N/A**

**V. CONTACTS**

**Pre-Implementation Contact(s):** Patricia Brocato-Simons, 410-786-0261 or Patricia.Brocatosimons@cms.hhs.gov

**Post-Implementation Contact(s):** Contact your Contracting Officer's Representative (COR).

**VI. FUNDING**

**Section A: For Medicare Administrative Contractors (MACs):**

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

**ATTACHMENTS: 2**

# Medicare National Coverage Determinations Manual

## Chapter 1, Part 1 (Sections 10 – 80.12) Coverage Determinations

Table of Contents  
*(Rev. 12112; Issued: 06-29-23)*

### Transmittals for Chapter 1, Part 1

20.33- *Transcatheter Edge-to-Edge Repair (TEER) for Mitral Valve Regurgitation*

## 20.4 – Implantable Cardioverter Defibrillators (ICDs)

*(Rev. 12112; Issued: 06-29-23; Effective: 07-31-23; Implementation: 07-31-23)*

### A. General

An implantable cardioverter defibrillator (ICD) is an electronic device designed to diagnose and treat life-threatening ventricular tachyarrhythmias.

### B. Nationally Covered Indications

Effective for services performed on or after February 15, 2018 CMS has determined that the evidence is sufficient to conclude that the use of ICDs, (also referred to as defibrillators) is reasonable and necessary:

1. Patients with a personal history of sustained ventricular tachyarrhythmia (VT) or cardiac arrest due to ventricular fibrillation (VF). Patients must have demonstrated:
  - An episode of sustained VT, either spontaneous or induced by an electrophysiology (EP) study, not associated with an acute myocardial infarction (MI) and not due to a transient or reversible cause; or
  - An episode of cardiac arrest due to VF, not due to a transient or reversible cause.
2. Patients with a prior MI and a measured left ventricular ejection fraction (LVEF)  $\leq 0.30$ . Patients must not have:
  - New York Heart Association (NYHA) classification IV heart failure; or,
  - Had a coronary artery bypass graft (CABG), or percutaneous coronary intervention (PCI) with angioplasty and/or stenting, within the past 3 months; or,
  - Had an MI within the past 40 days; or,
  - Clinical symptoms and findings that would make them a candidate for coronary revascularization.

For these patients identified in B2, a formal shared decision making encounter must occur between the patient and a physician (as defined in Section 1861(r)(1) of the Social Security Act (the Act)) or qualified non-physician practitioner (meaning a physician assistant, nurse practitioner, or clinical nurse specialist as defined in §1861(aa)(5) of the Act) using an evidence-based decision tool on ICDs prior to initial ICD implantation. The shared decision making encounter may occur at a separate visit.

3. Patients who have severe, ischemic, dilated cardiomyopathy but no personal history of sustained VT or cardiac arrest due to VF, and have NYHA Class II or III heart failure, LVEF  $\leq 35\%$ . Additionally, patients must not have:
  - Had a CABG, or PCI with angioplasty and/or stenting, within the past 3 months; or,
  - Had an MI within the past 40 days; or,
  - Clinical symptoms and findings that would make them a candidate for coronary revascularization.

For these patients identified in B3, a formal shared decision making encounter must occur between the patient and a physician (as defined in Section 1861(r)(1) of the Act) or qualified non-physician practitioner (meaning a physician assistant, nurse practitioner, or clinical nurse specialist as defined in §1861(aa)(5) of the Act) using an evidence-based decision tool on ICDs prior to initial ICD implantation. The shared decision making encounter may occur at a separate

visit.

4. Patients who have severe, non-ischemic, dilated cardiomyopathy but no personal history of sustained VT *or cardiac arrest due to VF, and have* NYHA Class II or III heart failure, LVEF  $\leq$  35%, been on optimal medical therapy for at least 3 months. Additionally, patients must not have:
  - Had a CABG or PCI with angioplasty and/or stenting, within the past 3 months; or,
  - Had an MI within the past 40 days; or,
  - Clinical symptoms and findings that would make them a candidate for coronary revascularization.

For these patients identified in B4, a formal shared decision making encounter must occur between the patient and a physician (as defined in Section 1861(r)(1) of the Act) or qualified non-physician practitioner (meaning a physician assistant, nurse practitioner, or clinical nurse specialist as defined in §1861(aa)(5) of the Act) using an evidence-based decision tool on ICDs prior to initial ICD implantation. The shared decision making encounter may occur at a separate visit.

5. Patients with documented, familial or genetic disorders with a high risk of life-threatening tachyarrhythmias (sustained VT or VF), to include, but not limited to, long QT syndrome or hypertrophic cardiomyopathy.

For these patients identified in B5, a formal shared decision making encounter must occur between the patient and a physician (as defined in Section 1861(r)(1) of the Act) or qualified non-physician practitioner (meaning a physician assistant, nurse practitioner, or clinical nurse specialist as defined in §1861(aa)(5) of the Act) using an evidence-based decision tool on ICDs prior to initial ICD implantation. The shared decision making encounter may occur at a separate visit.

6. Patients with an existing ICD may receive an ICD replacement if it is required due to the end of battery life, elective replacement indicator (ERI), or device/lead malfunction.

For each of the 6 covered indications above, the following additional criteria must also be met:

1. Patients must be clinically stable (e.g., not in shock, from any etiology);
2. LVEF must be measured by echocardiography, radionuclide (nuclear medicine) imaging, cardiac magnetic resonance imaging (MRI), or catheter angiography;
3. Patients must not have:
  - Significant, irreversible brain damage; or,
  - Any disease, other than cardiac disease (e.g., cancer, renal failure, liver failure) associated with a likelihood of survival less than 1 year; or,
  - Supraventricular tachycardia such as atrial fibrillation with a poorly controlled ventricular rate.

Exceptions to waiting periods for patients that have had a CABG, or PCI with angioplasty and/or stenting, within the past 3 months, or had an MI within the past 40 days:

Cardiac Pacemakers: Patients who meet all CMS coverage requirements for cardiac pacemakers, and who meet the criteria in this national coverage determination for an ICD, may receive the combined devices in one procedure, at the time the pacemaker is clinically indicated;

Replacement of ICDs: Patients with an existing ICD may receive an ICD replacement if it is required due to the end of battery life, ERI, or device/lead malfunction.

### **C. Nationally Non-Covered Indications**

N/A

### **D. Other**

For patients that are candidates for heart transplantation on the United Network for Organ Sharing (UNOS) transplant list awaiting a donor heart, coverage of ICDs, as with cardiac resynchronization therapy, as a bridge-to-transplant to prolong survival until a donor becomes available, is determined by the local Medicare Administrative Contractors (MACs).

All other indications for ICDs not currently covered in accordance with this decision may be covered under Category B investigational device exemption (IDE) trials (42 CFR 405.201).

(This NCD last reviewed February 2018.)

## **20.33 - *Transcatheter Edge-to-Edge Repair (TEER) for Mitral Valve Regurgitation*** ***(Rev. 12112; Issued: 06-29-23; Effective: 07-31-23; Implementation: 07-31-23)***

### **A. General**

Transcatheter Edge-to-Edge Repair (TEER) of the mitral valve is used in the treatment of mitral regurgitation. TEER approximates the anterior and posterior mitral valve leaflets by grasping them with a clipping device in an approach similar to a treatment developed in cardiac surgery called the Alfieri stitch.

### **B. Nationally Covered Indications**

The Centers for Medicare & Medicaid Services (CMS) covers TEER of the mitral valve under Coverage with Evidence Development (CED) with the following conditions:

- A. For the treatment of symptomatic moderate-to-severe or severe functional mitral regurgitation (MR) when the patient remains symptomatic despite stable doses of maximally tolerated guideline-directed medical therapy (GDMT) plus cardiac resynchronization therapy, if appropriate, or for the treatment of significant symptomatic degenerative MR when furnished according to a Food and Drug Administration (FDA)-approved indication and when all of the following conditions are met:
  1. The procedure is furnished with a mitral valve TEER system that has received FDA premarket approval (PMA).
  2. The patient (preoperatively and postoperatively) is under the care of a heart team: a cohesive, multidisciplinary, team of medical professionals. The heart team concept embodies collaboration and dedication across medical specialties to offer optimal patient-centered care. The heart team must include the following members with experience and training as specified:
    - a. Cardiac surgeon
      - i. With  $\geq 20$  mitral valve surgeries per year or  $\geq 40$  over two years, 50% of which are mitral valve repairs; and,
      - ii. Who is board eligible or certified in cardiothoracic surgery or similar foreign equivalent.
    - b. Interventional cardiologist

- i. With professional experience of  $\geq 50$  career structural heart disease procedures; or  $\geq 30$  left-sided structural procedures per year; and,
    - ii. With participation in  $\geq 20$  career trans-septal interventions including 10 as primary or co-primary operator; and,
    - iii. Who is board eligible or certified in interventional cardiology or similar foreign equivalent.
  - c. Interventional echocardiographer (cardiologist or anesthesiologist)
    - i. With professional experience of  $\geq 10$  trans-septal guidance procedures and  $\geq 30$  structural heart procedures; and,
    - ii. Who is board eligible or certified in transesophageal echocardiography with advanced training as required for privileging by the hospital where the TEER is performed.
  - d. Heart failure cardiologist experienced in treating patients with advanced heart failure (only required for functional MR patients); and,
  - e. Providers from other physician groups as well as advanced patient practitioners, nurses, research personnel, and administrators.
- 3. Each patient's suitability for surgical mitral valve repair, TEER, or palliative therapy must be evaluated, documented, and made available to other heart team members. Additionally, for patients with functional MR, the heart team heart failure cardiologist must document that the patient has persistent symptoms despite maximally tolerated GDMT and cardiac resynchronization therapy, if appropriate, as described below:
  - a. For patients with functional MR: the heart team interventional cardiologist and heart team heart failure cardiologist independently evaluate the patient using information in the medical record and a face-to-face examination. To decrease patient burden, the heart team heart failure cardiologist may meet this requirement through a review of the patient's records and images if the patient has an established relationship with a cardiologist experienced in treating patients with advanced heart failure.
  - b. For patients with degenerative MR: the heart team interventional cardiologist and heart team cardiac surgeon must independently evaluate the patient using information in the medical record and a face-to-face examination.
- 4. An interventional cardiologist or cardiac surgeon from the heart team must perform the mitral valve TEER and an interventional echocardiographer from the heart team must perform transesophageal echocardiography during the procedure. The interventional echocardiographer may not also furnish anesthesia during the same procedure. The interventional cardiologist and cardiac surgeon may jointly participate in the intra-operative technical aspects of TEER as appropriate. All physicians who participate in the procedure must have device-specific training as required by the manufacturer.
- 5. Mitral valve TEERs must be furnished in a hospital with appropriate infrastructure and experience that includes, but is not limited to:
  - a. On-site heart valve surgery and interventional cardiology programs;
  - b. Post-procedure intensive care facility with personnel experienced in managing patients who have undergone open-heart procedures;
  - c. Hospital volume requirements below must be met and maintained:
    - i.  $\geq 20$  mitral valve surgical procedures for severe MR per year or  $\geq 40$  over two years, of which at least 10 (or 20 over two years) must be mitral valve repairs; and,
    - ii.  $\geq 2$  physicians with cardiac surgery privileges experienced in valvular surgery; and,
    - iii.  $\geq 1$  physician with interventional cardiology privileges; and,
    - iv.  $\geq 300$  percutaneous coronary interventions (PCIs) per year.
- 6. The heart team and hospital are participating in a prospective, national, audited registry that: 1) comprehensively enrolls TEER patients; 2) accepts all manufactured devices; 3) follows the patient for at least one year; and, 4) complies with relevant regulations relating to protecting human research subjects, including 45 Code of Federal Regulations (CFR) Part 46 and 21 CFR Parts 50 & 56.

The following outcomes must be tracked by the registry, and the registry must be designed to permit identification and analysis of patient, practitioner, and facility level variables that predict each of these outcomes:

- a. Stroke;
  - b. All-cause mortality;
  - c. Repeat TEER or other mitral procedures;
  - d. Transient Ischemic Attacks (TIAs);
  - e. Major vascular events;
  - f. Renal complications;
  - g. Functional capacity; and
  - h. Quality of Life (QoL).
7. The registry shall collect all data necessary and have a written executable analysis plan in place to address the following questions. Specifically, for the CED question d, this must be addressed through a composite metric. For the below CED questions (a-e), the results must be reported publicly as described in CED criterion k.
- a. When TEER procedures are performed outside a controlled clinical study, how do outcomes and adverse events compare to the pivotal clinical studies?
  - b. How do outcomes and adverse events in subpopulations compare to patients in the pivotal clinical studies?
  - c. What is the long-term ( $\geq 5$  year) durability of the device?
  - d. What are the long-term ( $\geq 5$  year) outcomes and adverse events?
  - e. How do the demographics of registry patients compare to the pivotal studies?

Consistent with section 1142 of the Act, the Agency for Healthcare Research and Quality (AHRQ) supports clinical research studies that CMS determines meet the above-listed standards and address the above-listed research questions.

- B. Mitral valve TEERs are covered for uses that are not expressly listed as an FDA-approved indication when performed within a clinical study that fulfills all of the following:
1. An interventional cardiologist or cardiac surgeon must perform the mitral valve TEER and an interventional echocardiographer must perform transesophageal echocardiography during the procedure. The interventional echocardiographer may not also furnish anesthesiology during the same procedure. The interventional cardiologist and cardiac surgeon may jointly participate in the intra-operative technical aspects of TEER as appropriate. All physicians who participate in the procedure must have device specific training as required by the manufacturer.
  2. As a fully-described, written part of its protocol, the clinical research trial must critically evaluate the following questions at 12 months or longer follow-up:
    - a. What is the rate of all-cause mortality in the intervention group?
    - b. What is the rate of re-operations (open surgical or transcatheter) of the mitral valve in the intervention group?
    - c. What is the rate of moderate-to-severe or severe MR in the intervention groups?
  3. As a fully-described, written part of its protocol, the clinical research study must critically evaluate not only each patient's quality of life pre- and post-TEER (minimum 1 year), but must also address at least one of the following questions:
    - a. What is the incidence of stroke?
    - b. What is the incidence of TIAs?

- c. What is the incidence of major vascular events?
  - d. What is the incidence of renal complications?
  - e. What is the incidence of worsening MR?
  - f. What is the change in quality of life after TEER?
  - g. What is the change in the patient's functional capacity after TEER?
4. The clinical study must adhere to the following standards of scientific integrity and relevance to the Medicare population:
- a. The principal purpose of the study is to test whether the item or service meaningfully improves health outcomes of affected beneficiaries who are represented by the enrolled subjects.
  - b. The rationale for the study is well supported by available scientific and medical evidence.
  - c. The study results are not anticipated to unjustifiably duplicate existing knowledge.
  - d. The study design is methodologically appropriate and the anticipated number of enrolled subjects is sufficient to answer the research question(s) being asked in the National Coverage Determination (NCD).
  - e. The study is sponsored by an organization or individual capable of completing it successfully.
  - f. The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found in the Code of Federal Regulations (CFR) at 45 CFR Part 46. If a study is regulated by the Food and Drug Administration (FDA), it is also in compliance with 21 CFR Parts 50 and 56. In addition, to further enhance the protection of human subjects in studies conducted under CED, the study must provide and obtain meaningful informed consent from patients regarding the risks associated with the study items and /or services, and the use and eventual disposition of the collected data.
  - g. All aspects of the research study are conducted according to appropriate standards of scientific integrity.
  - h. The study has a written protocol that clearly demonstrates adherence to the standards listed here as Medicare requirements.
  - i. The study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Such studies may meet this requirement only if the disease or condition being studied is life threatening as defined in 21 CFR §312.81(a) and the patient has no other viable treatment options.
  - j. The clinical research studies and registries are registered on the [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov) website by the principal sponsor/investigator prior to the enrollment of the first study subject. Registries are also registered in the Agency for Healthcare Quality (AHRQ) Registry of Patient Registries (RoPR).
  - k. The research study protocol specifies the method and timing of public release of all prespecified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 12 months of the study's primary completion date, which is the date the final subject had final data collection for the primary endpoint, even if the trial does not achieve its primary aim. The results must include number started/completed, summary results for primary and secondary outcome measures, statistical analyses, and adverse events. Final results must be reported in a publicly accessible manner; either in a peer-reviewed scientific journal (in print or on-line), in an on-line publicly accessible registry dedicated to the dissemination of clinical trial information such as [ClinicalTrials.gov](http://ClinicalTrials.gov), or in journals willing to publish in abbreviated format (e.g., for studies with negative or incomplete results).
  - l. The study protocol must explicitly discuss beneficiary subpopulations affected by the item or service under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria effect enrollment of these populations, and a plan for the retention and reporting of said populations on the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.

- m. The study protocol explicitly discusses how the results are or are not expected to be generalizable to affected beneficiary subpopulations. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability or Medicaid eligibility.

Consistent with section 1142 of the Act, the Agency for Healthcare Research and Quality (AHRQ) supports clinical research studies that meet the above-listed standards and address the above-listed research questions.

The principal investigator must submit the complete study protocol, identify the relevant CMS research question(s) that will be addressed, and cite the location of the detailed analysis plan for those questions in the protocol, plus provide a statement addressing how the study satisfies each of the standards of scientific integrity (a. through m. listed above), as well as the investigator's contact information, to the address below. The information will be reviewed, and approved studies will be identified on the CMS Website.

Director, Coverage and Analysis Group  
Re: TEER CED  
Centers for Medicare & Medicaid Services (CMS)  
7500 Security Blvd., Mail Stop S3-02-01  
Baltimore, MD 21244-1850

Email address for protocol submissions: [clinicalstudynotification@cms.hhs.gov](mailto:clinicalstudynotification@cms.hhs.gov)  
Email subject line: "CED TEER [name of sponsor/primary investigator]"

#### C. Nationally Non-Covered Indications

TEER of the mitral valve is not covered under the following circumstances:

1. For patients in whom existing co-morbidities would preclude the expected benefit from a mitral valve TEER procedure.
2. In patients with untreated severe aortic stenosis.

#### D. Other

CMS will consider published, peer-reviewed evidence periodically, following the effective date of this NCD and reconsider the policy when appropriate. The NCD will expire 10 years from the effective date if it is not reconsidered during that time. Upon expiration, coverage will be at the discretion of the Medicare Administrative Contractors.

**Medicare National Coverage Determinations Manual**  
**Chapter 1, Part 3 (Sections 170 – 190.34)**  
**Coverage Determinations**

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## **190.1 - Histocompatibility Testing**

*(Rev. 12112; Issued: 06-29-23; Effective: 07-31-23; Implementation: 07-31-23)*

Histocompatibility testing involves the matching or typing of the human leucocyte antigen (HLA). This testing is safe and effective when it is performed on patients:

- A.* In preparation for a kidney transplant;
- B.* In preparation for bone marrow transplantation;
- C.* In preparation for blood platelet transfusions (particularly where multiple infusions are involved); or
- D.* Who are suspected of having ankylosing spondylitis.

This testing is covered under Medicare when used for any of the indications listed in A, B, and C and if it is reasonable and necessary for the patient.

It is covered for ankylosing spondylitis in cases where other methods of diagnosis would not be appropriate or have yielded inconclusive results. Request documentation supporting the medical necessity of the test from the physician in all cases where ankylosing spondylitis is indicated as the reason for the test.

**Medicare National Coverage Determinations Manual**  
**Chapter 1, Part 4 (Sections 200 – 310.1)**  
**Coverage Determinations**

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**280.1 – Durable Medical Equipment Reference List (Effective May 5, 2005)**  
*(Rev. 12112; Issued: 06-29-23; Effective: 07- 31-23; Implementation: 07-31- 23)*

**Durable Medical Equipment Reference List**

<b>Item</b>	<b>Coverage</b>
*** Muscle Stimulators this manual.)	Covered for certain conditions (See §160.12 of
***	