Molecular Testing for HLA-B27 for Ankylosing Spondylitis

INDEPENDENT CARE HEALTH PLAN

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Medicare Advantage Medical Coverage Policy

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Related Documents

Please refer to CMS website for the most current applicable National Coverage Determination (NCD)/ Local Coverage Determination (LCD)/Local Coverage Article (LCA)/CMS Online Manual System/Transmittals.

Type	Title	ID Number	Jurisdiction Medicare	Applicable States/Territories

			Administrative Contractors (MACs)	
NCD	Histocompatibility Testing	190.1		

Description

Ankylosing spondylitis (AS) is a chronic inflammatory disease. It is a type of arthritis that affects the spine. AS can cause pain, stiffness and inflammation from the neck to the lower back and, in severe cases, can cause the vertebrae in the spine to fuse together. No specific laboratory tests are required to establish diagnosis, however, HLA-B positive status helps to support the diagnosis. Plain radiography of pelvis and sacroiliac joints is the initial imaging method. There are no true diagnostic criteria; however, classification criteria have been developed and are frequently used to aid diagnosis.[2] Diagnosis can be done using imaging or clinical criteria.[6]

HLA-B*27 (human leukocyte antigen) is a specific protein located on cell surfaces. The term HLA-B*27 is also used to refer to the gene that codes for the HLA-B*27 protein. The HLA-B*27 test determines the presence or absence of HLA-B*27 protein on the surface of an individual's white blood cells.

HLA-B*27 was initially identified using serological methods to detect the presence of HLA-B*27 antigen; however, this methodology is no longer used by United States laboratories. Today, DNA-based molecular techniques are used such as polymerase chain reaction (PCR) with restriction fragment length polymorphism (RFLP) analysis, sequence specific primer (SSP) and/or sequence-specific oligonucleotide probe (SSOP).

Coverage Determination

Humana follows the CMS requirement that only allows coverage and payment for services that are reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.

Genetic tests must demonstrate clinical utility, analytical and clinical validity and fulfill the CMS "reasonable and necessary" criteria. Analytic validity (test accurately identifies the gene variant), clinical validity (test identifies or predicts the clinically defined disorder) and clinical utility (test measurably improves clinical outcomes) of the genetic test is supported by generally accepted standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, specialty society recommendations, and views of physicians practicing in relevant clinical areas. The test must be ordered by a physician who is treating the beneficiary and the results will be used in the management of a beneficiary's specific medical problem.

For jurisdictions with no Medicare guidance for a particular test, Humana will utilize the MolDX program and Technical Assessments for molecular assays as the standard to evaluate clinical utility, analytical and clinical validity in conjunction with adhering to Medicare's reasonable and necessary requirement.

In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, Humana may consider the following criteria:

Please refer to the above CMS guidance for **molecular testing for HLA-B*27 for ankylosing spondylitis.**

The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically necessary and thus do not provide a clinical benefit. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.

Coverage Limitations

US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage

The following tests may not be considered a benefit (statutory exclusion)[7]:

- Tests considered screening in the absence of clinical signs and symptoms of disease that are not specifically identified by the law; **OR**
- Tests that confirm a diagnosis or known information; **OR**
- Tests to determine risk for developing a disease or condition; **OR**
- Tests performed to measure the quality of a process; **OR**
- Tests without diagnosis specific indications; **OR**
- Tests identified as investigational by available literature and/or the literature supplied by the developer and are not a part of a clinical trial

These treatments and services fall within the Medicare program's statutory exclusion that prohibits payment for items and services that have not been demonstrated to be reasonable and necessary for the diagnosis and treatment of illness or injury (§1862(a)(1) of the Act). Other services/items fall within the Medicare program's statutory exclusion at 1862(a)(12), which prohibits payment.

The following **services/items** will not be considered medically reasonable and necessary:

- Genetic tests that have not demonstrated clinical utility, analytical and clinical validity via the MolDX Program, **OR**

- HLA typing prior to standard work up for AS (blood work, family history, physical examination, radiography or MRI)

A review of the current medical literature shows that the evidence is insufficient to determine that this service is standard medical treatment for these indications. There remains an absence of randomized blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of this service in clinical management for these indications.

Summary of evidence:

Evidence shows that while many individuals with AS carry the HLA-B27 gene variant, testing positive for it does not mean the individual will develop AS.[8] There are no true diagnostic criteria; however, classification criteria have been developed and are frequently used to aid diagnosis.[2] Diagnosis can be done using Assessment of SpondyloArthritis International Society (ASAS) imaging or clinical criteria. To fulfill the imaging criteria, patients must have radiographic or MRI evidence of sacroiliitis plus at least 1 spondyloarthritis feature. To fulfill the clinical criteria, patients must have HLAB27 plus at least 2 separate spondyloarthritis features. ASAS spondyloarthritis features include the following:

- Arthritis
- Dactylitis (inflammation of a digit [either a finger or toe])
- Good response to nonsteroidal anti-inflammatory drugs
- Elevated C-reactive protein
- Enthesitis of the heel
- Family history of spondyloarthritis
- History of inflammatory back pain
- Inflammatory bowel disease
- Presence of HLA-B27
- Psoriasis
- Uveitis (inflammation/swelling of the colored portion of the eye)[6]

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments

81374	HLA Class I typing, low resolution (eg, antigen equivalents); one antigen equivalent (eg, B*27), each	
CPT® Category III Code(s)	**Description**	**Comments**
No code(s) identified		
HCPCS Code(s)	**Description**	**Comments**
No code(s) identified		

References

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