Reimbursement Policy

β - Hemolytic Streptococcus Testing

POLICY DESCRIPTION | INDICATIONS AND/OR LIMITATIONS OF COVERAGE | APPLICABLE STATE AND FEDERAL REGULATIONS | APPLICABLE CPT/HCPCS PROCEDURE CODES | EVIDENCE-BASED SCIENTIFIC REFERENCES |

I. Policy Description

Streptococcus are Gram-positive, catalase-negative bacteria that are further divided into α-hemolytic, such as *S. pneumoniae* and *S. mutans*; β-hemolytic, such as *S. pyogenes* (Group A), *S. agalactiae* (Group B), and *S. dysgalactiae subsp equisimilis* (Groups C and G); and γ-hemolytic, such as *Enterococcus faecalis* and *E. faecium* (Wessels, 2024). Streptococcal infections can be manifested in a variety of pathologies, including cutaneous infections, pharyngitis, acute rheumatic fever, pneumonia, postpartum endometritis, and toxic shock syndrome to name a few. Streptococcal infections can be identified using bacterial cultures obtained from blood, saliva, pus, mucosal, and skin samples as well as rapid antigen diagnostic testing (RADT) and nucleic acid-based methodologies (Chow, 2023; Wessels, 2024).

For prenatal screening of Group B Streptococcus, please review policy AHS-G2035.

II. Indications and/or Limitations of Coverage

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request. Specifications pertaining to Medicare and Medicaid can be found in the "Applicable State and Federal Regulations" section of this policy document.

1) For the detection of a streptococcal infection causing respiratory illness, rapid antigen detection testing or bacterial culture testing from a throat swab **MEETS COVERAGE CRITERIA** when **one** of the following conditions is met:

   a) When the individual has a modified Centor criteria score of 3 or greater (see Note below).

   b) When the individual is suspected of having bacterial pharyngitis in the absence of viral features, (e.g., cough, oral ulcers, rhinorrhea).

   c) Bacterial culture testing following a negative rapid antigen diagnostic test (RADT) in a symptomatic child or adolescent.

2) Blood culture testing for a streptococcal infection **MEETS COVERAGE CRITERIA** when one of the following conditions is met:

   a) For individuals who fail to demonstrate clinical improvement.

Reimbursement Policy

b) For individuals who have progressive symptoms or clinical deterioration after the initiation of antibiotic therapy.

c) In cases of suspected prosthetic joint infection.

3) In cases of skin and/or soft tissue infections, bacterial culture testing for a streptococcal infection from a skin swab or from pus **MEETS COVERAGE CRITERIA**.

4) For individuals with suspected acute rheumatic fever (ARF) or post-streptococcal glomerulonephritis (PSGN), the following testing **MEETS COVERAGE CRITERIA**:

a) Serological titer testing.

b) Anti-streptolysin O immunoassay.

c) Hyaluronidase activity or anti-hyaluronidase immunoassay.

d) Streptokinase activity or anti-streptokinase immunoassay.

5) In cases of suspected viral pharyngitis, bacterial culture testing for streptococci from a throat swab **DOES NOT MEET COVERAGE CRITERIA**.

6) Except in cases of asymptomatic children under the age of three years who have a mitigating circumstance (including a symptomatic family member), RADT for a streptococcal infection **DOES NOT MEET COVERAGE CRITERIA** in any of the following situations:

a) As a follow-up test for individuals who have had either a bacterial culture test or a nucleic acid test for a streptococcal infection.

b) As a screening method in an asymptomatic patient.

c) For individuals with suspected viral pharyngitis.

7) For all situations not described above, serological titer testing **DOES NOT MEET COVERAGE CRITERIA**.

8) Simultaneous ordering of **both** direct probe and amplification probe for the same organism in a single encounter **DOES NOT MEET COVERAGE CRITERIA**.

The following does not meet coverage criteria due to a lack of available published scientific literature confirming that the test(s) is/are required and beneficial for the diagnosis and treatment of an individual's illness.

9) For all situations not described above, testing with an anti-streptolysin O immunoassay, a hyaluronidase activity or anti-hyaluronidase immunoassay, **or** a streptokinase activity or anti-streptokinase immunoassay **DOES NOT MEET COVERAGE CRITERIA**.

10) For all situations, the following tests **DO NOT MEET COVERAGE CRITERIA**:

a) Panel tests that screen and identify multiple streptococcal strains (*S. pyogenes* [group A], *S. agalactiae* [group B], *S. dysgalactiae* [groups C/G], α-hemolytic streptococcus, and/or γ-hemolytic streptococcus), using either immunoassay or nucleic acid-based assays (e.g., Solana Strep Complete Assay, Lyra Direct Strep Assay).

b) MALDI-TOF identification of streptococcus.

c) The quantification of any strain of streptococcus using nucleic acid amplification, including PCR.

d) Nicotinamide-adenine dinucleotidase activity or anti-nicotinamide-adenine immunoassay.

NOTE: Centor criteria includes tonsillar exudates, tender anterior cervical lymphadenopathy, fever, and absence of cough with each criterion being worth one point (Chow, 2023).

III. Applicable State and Federal Regulations

DISCLAIMER: If there is a conflict between this Policy and any relevant, applicable government policy for a particular member [e.g., Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs) for Medicare and/or state coverage for Medicaid], then the government policy will be used to make the determination. For the most up-to-date Medicare policies and coverage, please visit the Medicare search website: https://www.cms.gov/medicare-coverage-database/search.aspx. For the most up-to-date Medicaid policies and coverage, visit the applicable state Medicaid website.

Food and Drug Administration (FDA)

The FDA approved the Lyra Direct Strep Assay (k133833) on 04/16/2014 and reclassified it on 07/11/2014. It is a "Real-Time PCR *in vitro* diagnostic test for the qualitative detection and differentiation of Group A β -hemolytic *Streptococcus* (*Streptococcus pyogenes*) and pyogenic Group C and G β -hemolytic *Streptococcus* nucleic acids isolated from throat swab specimens obtained from patients with signs and symptoms of pharyngitis, such as sore throat. The assay does not differentiate between pyogenic Groups C and G β-hemolytic *Streptococcus"* (Hojvat, 2014). The FDA has also approved the Solana Strep Complete Assay by Quidel that is "an in vitro diagnostic test for the detection of Group A, C and G beta- hemolytic *Streptococcus* in throat swab specimens from symptomatic patients" on 10/25/2016 (K162274) (FDA, 2016).

Reimbursement Policy

On 03/06/2019, the FDA approved GenePOC's Strep A assay to be performed using GenePOC's Revogene instrument as a "single-use test for qualitative detection of *Streptococcus pyogenes* (group A *Streptococcus*-GAS) nucleic acids from throat swab specimens obtained from patients with signs and symptoms of pharyngitis" (FDA, 2019).

On November 9, 2020, the FDA approved Mesa Biotech, Inc.'s Accula™ Strep A Test, which is a semi-automated, colorimetric polymerase chain reaction (PCR) nucleic acid amplification test "to qualitatively detect Streptococcus pyogenes (Group A βhemolytic Streptococcus, Strep A) bacterial nucleic acid from unprocessed throat swabs that have not undergone prior nucleic acid extraction" (FDA, 2020).

Many labs have developed specific tests that they must validate and perform in house. These laboratory-developed tests (LDTs) are regulated by the Centers for Medicare and Medicaid (CMS) as high-complexity tests under the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88). LDTs are not approved or cleared by the U. S. Food and Drug Administration; however, FDA clearance or approval is not currently required for clinical use.

IV. Applicable CPT/HCPCS Procedure Codes

CPT	Code Description
86060	Antistreptolysin 0; titer
86063	Antistreptolysin 0; screen
86215	Deoxyribonuclease, antibody
86317	Immunoassay for infectious agent antibody, quantitative, not otherwise specified
86318	Immunoassay for infectious agent antibody(ies), qualitative or semiquantitative, single step-method (eg, reagent strip);
87040	Culture, bacterial; blood, aerobic, with isolation and presumptive identification of isolates (includes anaerobic culture, if appropriate)
87070	Culture, bacterial; any other source except urine, blood or stool, aerobic, with isolation and presumptive identification of isolates
87071	Culture, bacterial; quantitative, aerobic with isolation and presumptive identification of isolates, any source except urine, blood or stool

87077	Culture, bacterial; aerobic isolate, additional methods required for definitive identification, each isolate
87081	Culture, presumptive, pathogenic organisms, screening only;
87430	Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative; Streptococcus, group A
87650	Infectious agent detection by nucleic acid (DNA or RNA); Streptococcus, group A, direct probe technique
87651	Infectious agent detection by nucleic acid (DNA or RNA); Streptococcus, group A, amplified probe technique
87652	Infectious agent detection by nucleic acid (DNA or RNA); Streptococcus, group A, quantification
87797	Infectious agent detection by nucleic acid (DNA or RNA), not otherwise specified; direct probe technique, each organism
87798	Infectious agent detection by nucleic acid (DNA or RNA), not otherwise specified; amplified probe technique, each organism
87799	Infectious agent detection by nucleic acid (DNA or RNA), not otherwise specified; quantification, each organism
87880	Infectious agent antigen detection by immunoassay with direct optical (ie, visual) observation; Streptococcus, group A

Procedure codes appearing in Medical Policy documents are included only as a general reference tool for each policy. They may not be all-inclusive.

V. Evidence-based Scientific References

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