Clinical Policy: Carrier Screening in Pregnancy

Reference Number: CP.MP.83
Last Review Date: 05/19

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

This policy outlines medical necessity criteria for cystic fibrosis (CF) and spinal muscular atrophy (SMA) carrier testing.

Policy/Criteria

I. It is the policy of health plans affiliated with Centene Corporation® that CF carrier screening (CPT® code 81220) or SMA carrier screening (81329) is **medically necessary** for women who are pregnant and meet the following criteria:
   A. No prior CF or SMA screening results are available, and
   B. Pregnancy < 23 weeks gestation, and
   C. Underwent pretest counseling.

II. It is the policy of Centene Corporation that CF or SMA carrier screening anytime other than during pregnancy and for requests for CF screening CPT® codes 81221 – 81224 during pregnancy is **medically necessary** when meeting the most current version of the relevant nationally recognized decision support tools.

Authorization Protocols

Requests for prior authorization will be accepted up to 10 business days after specimen collection and reviewed for medical necessity based on the above stated criteria.

Background

CF is a genetic disorder that causes the body to make thick, sticky secretions that clog the lungs and other organs such as the digestive system. More than 10 million Americans are carriers of a defective CF gene and show no symptoms of the disease. CF is a recessive disorder, therefore, an abnormal gene must be inherited from both parents in order for the child to develop CF. Carrier testing may provide an early indication as to whether a fetus might either be a carrier or might develop CF.

SMA is an autosomal recessive disorder that causes degeneration of spinal cord motor neurons which leads to atrophy of the skeletal muscles. People with SMA experience overall weakness in the voluntary muscles, as well as trouble breathing and swallowing. Approximately 6 million Americans are carriers for SMA, with 1 in 6,000 to 1 in 10,000 live births being diagnosed with SMA. SMA is the leading genetic cause of infant mortality. Most cases of SMA result from both parents being carriers, but approximately 2% of cases are the result of a new gene mutation.

For either CF or SMA, if the maternal screening test is positive, the father of the baby must also be tested to determine if he is a carrier. If negative, no further testing is needed. If both the mother and father test positive for a defective gene, the infant will most likely be a carrier like the parents (50% chance). However, there is a 25% chance that the infant will have the disease.

If both parents are carriers, chorionic villus sampling or amniocentesis can be performed to see whether the fetus has the disease. Since these are both invasive procedures that carry a slight risk to the fetus, further testing should only be performed if and when the course of the pregnancy will be altered based on results of the testing.

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2019, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

CPT® Codes	Description
81220	CFTR (cystic fibrosis transmembrane conductance regulator (eg. Cystic fibrosis) gene analysis; common variants (eg. ACMG/ACOG guidelines)
81221	known family variants
81222	Duplication/deletion variants
81223	Full gene sequence
81224	Intron 8 poly-T analysis (eg, male infertility)
81329	SMN1 (survival of motor neuron 1, telomeric) (eg, spinal muscular atrophy) gene analysis; dosage/deletion analysis (eg, carrier testing), includes SMN2 (survival of motor neuron 2, centromeric) analysis, if performed

Reviews, Revisions, and Approvals	Date	Approval Date
Initial approval date		07/13
References reviewed	07/15	07/15
References reviewed and updated. Minor wording changes made to background.	07/16	07/16
Removed requirement for biological father to be available for testing. Added 5 day allowance for authorization.	10/16	10/16
Changed title to reflect content change. Added criteria and background information for carrier screening for SMA.	07/17	07/17
References reviewed	05/18	05/18
Replaced 81401 generic molecular path code with 81329, the new 2019 code for SMA carrier screening	01/19	
Updated authorization protocol to allow for 10 business days retro review instead of 5. For clarification, revised I.B to state Pregnancy < 23 weeks gestation rather than ≤ 22 weeks gestation. References reviewed and updated.	04/19	05/19

References

1. The American College of Obstetricians and Gynecologists. Carrier screening for genetic conditions. Committee Opinion, Committee on Genetics, No 691, March 2017. Reaffirmed 2019
2. The American College of Obstetricians and Gynecologists. Frequently asked questions FAQ171 Pregnancy. Cystic Fibrosis: Prenatal Screening and Diagnosis. June 2017. Accessed online at: http://www.acog.org/~/media/For%20Patients/faq171.pdf?dmc=1&ts=20130624T1134297985.
3. Cystic Fibrosis Foundation. CF Genetics. Accessed online at: http://www.cff.org/AboutCF/Testing/Genetics/.
4. Spinal Muscular Atrophy Foundation. Overview. Accessed online at: http://www.smafoundation.org/about-sma/
5. The American College of Obstetricians and Gynecologists. Frequently asked questions FAQ179. Pregnancy. Carrier Screening. Dec 2018. Accessed at: https://www.acog.org/Patients/FAQs/Carrier-Screening
6. The American College of Obstetricians and Gynecologists. Frequently asked questions FAQ197. Pregnancy. Carrier Screening for Spinal Muscular Atrophy. Oct 2018. Accessed at: https://www.acog.org/Patients/FAQs/Carrier-Screening-for-Spinal-Muscular-Atrophy
7. The American College of Obstetricians and Gynecologists. Carrier Screening in the Age of Genomic Medicine. No.690. March 2017. Reaffirmed 2019. Accessed April 26, 2019 at: https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Genetics/Carrier-Screening-in-the-Age-of-Genomic-Medicine?IsMobileSet=false

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.