



Policy: GG.1109
Title: **CalOptima Health and Health Network Newborn and Prenatal Genetic Screening Services**
Department: Medical Management
Section: Utilization Management

CEO Approval: /s/ Michael Hunn 12/20/2024

Effective Date: 02/01/2002

Revised Date: 12/01/2024

Applicable to: ☒ Medi-Cal
☒ OneCare
☐ PACE
☐ Administrative

I. PURPOSE

This policy outlines newborn and prenatal genetic screening services for Members, as mandated by state law.

II. POLICY

- A. CalOptima Health and Health Network Providers and Practitioners shall provide newborn and prenatal genetic screening, in accordance with state law and the most recent standards or guidelines of the American College of Obstetricians and Gynecologists (ACOG), to ensure that pregnant women and newborns are provided timely and effective genetic disease prevention, early detection, as well as diagnosis, treatment, education and counseling services.
- B. Pursuant to the California Department of Public Health's (CDPH) Prenatal Screening (PNS) Program, a pregnant Member seen for prenatal care prior to twenty (20) weeks gestation shall be offered prenatal blood testing by her Practitioner.
- C. Member participation in the California PNS Program is voluntary.
- D. A pregnant Member over thirty-five (35) years of age may choose to have a diagnostic amniocentesis performed, as authorized, by her Health Network or CalOptima Health Direct Practitioner.
- E. CalOptima Health and its contracted Health Networks shall ensure that a pregnant Member is informed that newborns must be screened for certain treatable hereditary disorders.
- F. CalOptima Health and its contracted Health Networks shall ensure that all Practitioners and relevant support staff delivering perinatal or pediatric services are knowledgeable about the requirements of the Newborn Screening (NBS) Program, the Expanded Alpha Fetoprotein (AFP) Program, and mandated genetic disorder reporting requirements.

III. PROCEDURE

A. Prenatal Screening for Pregnant Members

1. A perinatal Practitioner shall provide a PNS education booklet and offer the voluntary expanded prenatal screening program to a pregnant Member whose prenatal care began prior to twenty (20) weeks gestation. The PNS education booklets are specific to women who will be less than thirty-five (35) years of age at term, and women who will be thirty-five (35) years of age or older at term.
2. A perinatal Practitioner shall provide a pregnant Member with a copy of the CDPH document “Important Information for Parents,” as mandated by state law.
3. A perinatal Practitioner shall record a Member’s identification (ID) number on the state-provided test request form.
4. A perinatal Practitioner shall document a Member’s consent, or refusal, to participate in the PNS program in the Member’s Medical Record.
5. For a Medi-Cal Member, a perinatal Practitioner shall draw a specimen for the prenatal screening tests and send it to an appropriate DHCS-designated lab for a pregnant Member who agrees to participate in the program prior to twenty (20) weeks gestation. A perinatal Practitioner may also draw a specimen for open neural tube defects, abdominal wall defects, trisomy 21 (Down syndrome), and trisomy 18, based on the Member’s age and serum values.
6. DHCS Designated Labs Services for Medi-Cal Members
 - a. A DHCS-designated lab shall perform the following Triple Marker Screening tests: AFP, unconjugated estriol (UE), and human chorionic gonadotrophin (HCG).
 - b. A DHCS-designated lab shall process the specimen for open neural tube defects, abdominal wall defects, trisomy 21 (Down syndrome), and trisomy 18, if submitted.
 - c. Positive screening test results are reported to the DHCS Expanded AFP Coordinator.
 - d. DHCS-designated lab services are billed to the Medi-Cal Fee-for-Service program.
7. The PNS Coordinator shall notify the perinatal Practitioner of a positive screening.
8. The Health Network and CalOptima Health prenatal Practitioners shall coordinate services with the follow-up services provided for Members by the PNS program.
 - a. The PNS program shall provide follow-up diagnostic services for women testing positive and at-risk for birth defects.
 - b. Tests are offered through state-approved Prenatal Diagnosis Centers (PDC) and include genetic counseling, amniocentesis, and amniotic fluid analysis, including karyotype.
 - c. Follow-up diagnostic services provided by the PNS program are billed to the Medi-Cal Fee-for-Service program.

9. Health Networks and CalOptima Health Practitioners shall provide for all services Medically Necessary for a pregnant Member, including diagnostic amniocentesis, regardless of the results of the PNS testing.

B. Newborn Screening

1. A newborn is screened for a series of treatable hereditary disorders including PKU, galactosemia, hypothyroidism, sickle cell disease, and related hemoglobinopathies, prior to discharge from the hospital of birth.
2. A perinatal Practitioner shall obtain required blood specimens, utilizing DHCS-approved specimen collection forms.
3. A perinatal Practitioner shall send specimens to DHCS-approved newborn screening labs.
4. DHCS-approved newborn screening lab services are billed to the hospital of birth, or to the attending Physician, or Certified Nurse Midwife, in the case of an out-of-hospital birth.
5. Health Networks and CalOptima Health shall coordinate reimbursement to perinatal Practitioners for the newborn screening tests performed on Members in accordance with CalOptima Health Policy FF.2001: Claims Processing for Covered Services Rendered to CalOptima Health Direct-Administrative Members, CalOptima Health Community Network Members, or Members Enrolled in a Shared Risk Group; and the respective Health Network's claims policies.
6. DHCS-approved area genetics centers shall notify the Member's Primary Care Practitioner (PCP) of presumptive positive results and follow-up test results.
7. Health Network or CalOptima Health Practitioners shall refer a newborn Member with confirmed positive tests to the California Children's Services (CCS) Program, in accordance with CalOptima Health Policy GG.1101: California Children's Services (CCS)/Whole-Child Model-Coordination with County CCS Program.
8. The Health Networks and CalOptima Health are responsible for the provision of all WCM-related medical services for the Member, and coordination of care with the County CCS program, in accordance with CalOptima Health Policy GG.1101: California Children's Services (CCS)/Whole-Child Model-Coordination with County CCS Program.
9. Forms may be ordered from California Prenatal Screening (PNS) Program at the following address:

Prenatal Screening Program Supplies
California Department of Public Health
850 Marina Bay Parkway F175
Richmond CA 94804-6403

Telephone: (877) 984-8450
Facsimile: (877) 984-8650
Email: PNSsupplies@cdph.ca.gov

IV. ATTACHMENT(S)

Not Applicable

V. REFERENCE(S)

- A. California Prenatal Screening (PNS) Program
- B. CalOptima Health Contract for Health Care Services
- C. CalOptima Health Contract with the Centers for Medicare & Medicaid Services (CMS) for Medicare Advantage
- D. CalOptima Health Contract with the Department of Health Care Services (DHCS) for Medi-Cal
- E. CalOptima Health, Health Network Service Agreement
- F. CalOptima Health Policy FF.2001: Claims Processing for Covered Services Rendered to CalOptima Health Direct-Administrative Members, CalOptima Health Community Network Members or Members Enrolled in a Shared Risk Group
- G. CalOptima Health Policy GG.1101: California Children's Services (CCS)/Whole-Child Model-Coordination with County CCS Program
- H. Department of Health Care Services (DHCS) Numbered Letter: N.L.: 03-0518 Authorization of Genetic Testing
- I. Department of Health Care Services (DHCS) Medi-Cal Managed Care Division (MMCD) Policy Letter 98-006: Newborn and Prenatal Genetic Screening Services
- J. Department of Health Care Services (DHCS) Patient Information Consent Booklets
- K. Department of Health Care Services (DHCS) Publication 800 "Important Information for Parents-To-Be"
- L. Title 17, California Code of Regulations (CCR), §§6500 through 6508 and §§6521, 6523, 6525, 6527, 6529, 6531 and 6532
- M. Title 22, California Code of Regulations (CCR), §§51348.1 and 51529(d)
- N. The American College of Obstetricians and Gynecologists

VI. REGULATORY AGENCY APPROVAL(S)

Date	Regulatory Agency	Response
09/04/2015	Department of Health Care Services (DHCS)	Approved as Submitted

VII. BOARD ACTION(S)

Not Applicable

VIII. REVISION HISTORY

Action	Date	Policy	Policy Title	Program(s)
Effective	04/01/1998	GG.1109	CalOptima Direct and Health Network Newborn and Prenatal Genetic Screening Services	Medi-Cal
Revised	05/01/2007	GG.1109	CalOptima Direct and Health Network Newborn and Prenatal Genetic Screening Services	Medi-Cal
Revised	03/01/2015	GG.1109	CalOptima and Health Network Newborn and Prenatal Genetic Screening Services	Medi-Cal

Action	Date	Policy	Policy Title	Program(s)
Revised	11/01/2015	GG.1109	CalOptima and Health Network Newborn and Prenatal Genetic Screening Services	Medi-Cal OneCare OneCare Connect
Revised	10/01/2016	GG.1109	CalOptima and Health Network Newborn and Prenatal Genetic Screening Services	Medi-Cal OneCare OneCare Connect
Revised	12/01/2017	GG.1109	CalOptima and Health Network Newborn and Prenatal Genetic Screening Services	Medi-Cal OneCare OneCare Connect
Revised	06/01/2020	GG.1109	CalOptima and Health Network Newborn and Prenatal Genetic Screening Services	Medi-Cal OneCare OneCare Connect
Revised	04/01/2021	GG.1109	CalOptima and Health Network Newborn and Prenatal Genetic Screening Services	Medi-Cal OneCare OneCare Connect
Revised	12/31/2022	GG.1109	CalOptima Health and Health Network Newborn and Prenatal Genetic Screening Services	Medi-Cal OneCare
Revised	12/01/2023	GG.1109	CalOptima Health and Health Network Newborn and Prenatal Genetic Screening Services	Medi-Cal OneCare
Revised	12/01/2024	GG.1109	CalOptima Health and Health Network Newborn and Prenatal Genetic Screening Services	Medi-Cal OneCare

IX. GLOSSARY

Term	Definition
California Children's Services (CCS) Program	A State and county program providing Medically Necessary services to treat CCS-Eligible Conditions.
CalOptima Health Direct (COHD)	A direct health care program operated by CalOptima Health that includes both COHD- Administrative (COHD-A) and CalOptima Health Community Network (CHCN) and provides services to Members who meet certain eligibility criteria as described in Policy DD.2006: Enrollment in/Eligibility with CalOptima Health Direct.
Comprehensive Perinatal Service Provider	Any general practice physician, family practice physician, obstetrician-gynecologist, pediatrician, certified nurse midwife, family or pediatric nurse practitioner, alternative birth center, a group, any of whose Members is one of the above-named physicians, or any preferred provider organization or clinic holding a valid and current Medi-Cal provider number and certified pursuant to the standards of this section.
Comprehensive Perinatal Services Program (CPSP)	Services as defined in Welfare and Institutions Code, Section 14134.5, and Title 22, California Code of Regulations, Sections 51179 and 51348. For CalOptima Health Members, CPSP is incorporated into CalOptima Health's Perinatal Support Services.
Genetic Testing	Each cell in the body has a core structure that contains chromosomes. Each chromosome contains DNA. Genes are segments of DNA that determine specific traits, such as eye or hair color. A mutation is a change in the DNA. A gene mutation is a change in or damage to a gene. A mutation can be inherited or acquired during the lifetime as cells age or are exposed to certain chemicals. These changes can result in genetic disorders and genetic testing can identify changes or alterations in the genes that may cause illness or disease.
Health Network	A Physician Hospital Consortium (PHC), physician group under a shared risk contract, or health care service plan, such as a Health Maintenance Organization (HMO) that contracts with CalOptima Health to provide Covered Services to Members assigned to that Health Network.
Medical Record	<p><u>Medi-Cal</u>: The record of a Member's medical information including but not limited to, medical history, care or treatments received, test results, diagnoses, and prescribed medications.</p> <p><u>OneCare</u>: A medical record, health record, or medical chart in general is a systematic documentation of a single individual's medical history and care over time. The term 'Medical Record' is used both for the physical folder for each individual patient and for the body of information which comprises the total of each patient's health history. Medical records are intensely personal documents and there are many ethical and legal issues surrounding them such as the degree of third-party access and appropriate storage and disposal.</p>

Term	Definition
Medically Necessary/Medical Necessity	<p><u>Medi-Cal</u>: Reasonable and necessary Covered Services to protect life, to prevent significant illness or significant disability, or alleviate severe pain through the diagnosis or treatment of disease, illness, or injury, as required under W&I Code 14059.5(a) and Title 22 CCR Section 51303(a). Medically Necessary services shall include Covered Services necessary to achieve age-appropriate growth and development, and attain, maintain, or regain functional capacity.</p> <p>For Members under 21 years of age, a service is Medically Necessary if it meets the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) standard of medical necessity set forth in Section 1396d(r)(5) of Title 42 of the United States Code, as required by W&I Code 14059.5(b) and W&I Code Section 14132(v). Without limitation, Medically Necessary services for Members under 21 years of age include Covered Services necessary to achieve or maintain age-appropriate growth and development, attain, regain or maintain functional capacity, or improve, support or maintain the Member's current health condition. CalOptima Health shall determine Medical Necessity on a case-by-case basis, taking into account the individual needs of the child.</p> <p><u>OneCare</u>: Reasonable and necessary medical services to protect life, to prevent significant illness or significant disability, or alleviate severe pain through the diagnosis or treatment of disease, illness, or injury, as required under W&I Code 14059.5(a) and Title 22 CCR Section 51303(a). Medically Necessary services includes Medi-Cal Services necessary to achieve age-appropriate growth and development, and attain, maintain, or regain functional capacity.</p>
Member	A beneficiary enrolled in a CalOptima Health program.
Practitioner	A licensed independent practitioner including, but not limited to, a Doctor of Medicine (MD), Doctor of Osteopathy (DO), Doctor of Podiatric Medicine (DPM), Doctor of Chiropractic Medicine (DC), Doctor of Dental Surgery (DDS), Doctor of Psychology (PhD or PsyD), Licensed Clinical Social Worker (LCSW), Marriage and Family Therapist (MFT or MFCC), Nurse Practitioner (NP), Nurse Midwife, Physician Assistant (PA), Optometrist (OD), Registered Physical Therapist (RPT), Occupational Therapist (OT), or Speech and Language Therapist, furnishing Covered Services.
Primary Care Practitioner/Physician (PCP)	A Practitioner/Physician responsible for supervising, coordinating, and providing initial and primary care to Members and serves as the medical home for Members. The PCP is a general practitioner, internist, pediatrician, family practitioner, or obstetrician/gynecologist (OB/GYN). For Members who are Seniors or Persons with Disabilities or eligible for the Whole Child Model program, "Primary Care Practitioner" or "PCP" shall additionally mean any Specialty Care Provider who is a Participating Provider and is willing to perform the role of the PCP. A PCP may also be a non-physician Practitioner (NMP) (e.g., Nurse Practitioner [NP], Nurse Midwife, Physician Assistant [PA]) authorized to provide primary care services under supervision of a physician. For SPD or Whole Child Model beneficiaries, a PCP may also be a Specialty Care Provider or clinic.

Term	Definition
Provider	<p><u>Medi-Cal</u>: Any individual or entity that is engaged in the delivery of services, or ordering or referring for those services, and is licensed or certified to do so.</p> <p><u>OneCare</u>: Any Medicare provider (e.g., hospital, skilled nursing facility, home health agency, outpatient physical therapy, comprehensive outpatient rehabilitation facility, end-stage renal disease facility, hospice, physician, non-physician provider, laboratory, supplier, etc.) providing Covered Services under Medicare Part B. Any organization, institution, or individual that provides Covered Services to Medicare members. Physicians, ambulatory surgical centers, and outpatient clinics are some of the providers of Covered Services under Medicare Part B.</p>