Section (Primary Department) **Utilization Management**		**SUBJECT (Document Title)** **Genetic Screening – Newborn - CA**	
Effective Date 06/01/1996	**Date of Last Review** 02/08/2024	**Date of Last Revision** 01/25/2023	**Dept. Approval Date** 02/08/2024
Department Approval/Signature:			

Policy applies to health plans operating in the following State(s). Applicable products noted below.

Products				
☒ **Medicaid/CHIP**	☐ Arkansas	☐ Iowa	☐ Nevada	☐ Tennessee
☐ **Medicare/SNP**	☒ California	☐ Kentucky	☐ New Jersey	☐ Texas
☐ **MMP/Duals**	☐ Colorado	☐ Louisiana	☐ New York	☐ Virginia
	☒ District of Columbia	☐ Maryland	☐ New York (WNY)	☐ Washington
	☐ Florida	☐ Minnesota	☐ North Carolina	☐ West Virginia
	☐ Georgia	☐ Missouri	☐ Ohio	☐ Wisconsin
	☐ Indiana	☐ Nebraska	☐ South Carolina	

POLICY:

To ensure that newborns are provided timely and effective screening for treatable inheritable disorders, all newborns are offered blood testing through the California Department of Public Health's Newborn Screening Program, which is centrally managed by the California Genetic Disease Screening Program (GDSP).

DEFINITIONS:

None

PROCEDURE:

Per regulations issued by Department of Health Care Services (California Code of Regulations (CCR), Title 17, section 6500), all newborns are screened for the following series of treatable inheritable disorders prior to hospital discharge:

- Cystic fibrosis
- Endocrine disorders, such as hypothyroidism & adrenal hyperplasia
- Metabolic disorders, such as Phenylketonuria (PKU) & galactosemia
- Organic acid disorders
- Fatty acid oxidation disorders, such as carnitine transporter deficiency
- Hemoglobin disorders, such as sickle cell disease & thalassemia
- Severe Combined Immunodeficiency (SCID)

For out of hospital births, the attending physician or midwife ensures that the above lab tests are completed. A complete (and current) listing of Newborn Screening Area Service Centers may be found on the Department of Public Health, California Newborn Screening Program website which is listed in the References section below.

Anthem Medicaid (Anthem) providers inform pregnant members that newborns must be screened for those treatable hereditary disorders listed above. All Perinatal Care Physicians provide pregnant women with a copy of Department of Health Care Services (DHCS) of document titled "Important Information for Parents" which contains information concerning the California Newborn Screening Program.

The designated screening panel consists of the following laboratory tests:

- Radioimmune assay for T4
- Radioimmune assay for TSH
- Qualitative fluorometric blood phenylalanine
- Galactose – 1 – uridyltransferase
- Microbial inhibition assay for blood galactose

The specimen is usually collected prior to hospital discharge, or at an area service center (if collected after discharge), and sent to one of five area laboratories located throughout the state or at two laboratories at Northern and Southern Kaiser Permanente Medical Group. This helps to assure that the laboratories have the experience necessary to perform the work accurately.

The CA Genetics Disease Laboratory Branch (GDLB) contracts with seven screening laboratories and with six confirmatory laboratories. The laboratories listed below perform these tests and are reimbursed under contract by the GDLB.

The designated current screening laboratories are:

- Western Clinical Laboratory, Roseville, CA
- Allied Laboratories, Inc.; Mountain View, CA
- Genetic Disease Laboratory (GDL), Richmond, CA
- Permanente Medical Group, Inc., Regional Laboratory; Berkeley, CA
- Fresno Community Hospital Laboratory; Fresno, CA
- Quest Laboratory; West Hills, CA
- Memorial Medical Center of Long Beach; Long Beach, CA
- Southern California Permanente Regional Endocrinology Laboratory; Carson, CA

The current confirmatory laboratories are:

- Galactosemia Confirmatory Testing Laboratory, ARUP
- Biopterin Testing Laboratory, Children's Hospital of Los Angeles
- Hemoglobin Reference Laboratory, Children's Hospital of Oakland
- MS/MS Disorders Confirmatory Testing Laboratory, Quest Diagnostics Inc.
- Biotinidase Testing Laboratory, Stanford University Hospital & Clinic Stanford
- Cystic Fibrosis Testing Laboratory, Stanford University Hospital & Clinic Stanford

If there is an initial presumptive positive test result and/or follow-up tests conducted, the state-contracted area genetics center is will notify the infant's physician. Newborns with confirmed positive tests are California Children Services (CCS) eligible for that condition and are referred to the appropriate county CCS office. Please see Policy #CA_CAXX_004 "California Children's Services - CM Referral to and Coordination of Care with County CCS Offices" for additional information concerning CCS referrals.

REFERENCES:

- CA Health & Safety Code: 124975-124996, 125050-125070, 125000-125001
- California Code of Regulations, Title 17, sections 6500 & 6521
- California Department of Public Health. (2021). California Newborn Screening Program. Retrieved from http://www.dhcs.ca.gov/services/nhsp/Pages/default.aspx
- Policy #CA_CAXX_004 "California Children's Services - CM Referral to and Coordination of Care with County CCS Offices"

RESPONSIBLE DEPARTMENT:

Primary Department:
Utilization Management (UM)

Secondary Department(s):
Case Management (CM)

EXCEPTIONS:

None

REVISION HISTORY:

Review Date	Changes
02/08/24	• Annual Review—no changes
01/25/23	• Annual Review • Updated policy name from "Genetic Screening – Newborn" to "Genetic Screening – Newborn – CA" • Updated Primary Department section from "Medical Management: Utilization Management (UM) & Case Management (CM)" to "Utilization Management (UM)" to match primary department in header • Added Secondary Department(s) sub-header under Responsible

Review Date	Changes
	Departments section; Added "Case Management (CM)" as a secondary department
02/03/22	• Annual Review, updated references and placed in alphabetical order
01/27/21	• Annual Review, updated references
01/29/20	• Annual Review, updated references
01/30/19	• Annual Review, no changes
01/30/18	• Annual Review, updated references
01/30/17	• Annual review. Updated dates on state website to 2017
02/17/16	• Updated dates on state website to 2016
03/13/15	• Removed Healthy Families • Updated dates on state website to 2015
03/12/14	• Review only.
02/01/13	• Corrected formatting and grammar • Removed specific listing of Expanded AFP Follow-up Centers in and added a link to the CA Dept. Public Health website where current list of service centers can be located. • Updated current laboratories contracted by the GDLB • Updated references
03/29/12	• Updated references