



MEDICAL COVERAGE GUIDELINES  
SECTION: LABORATORY

ORIGINAL EFFECTIVE DATE: 08/01/12  
LAST REVIEW DATE: 09/18/18  
LAST CRITERIA REVISION DATE: 09/18/18  
ARCHIVE DATE:

---

## NEWBORN SCREENING TESTS

---

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Medical Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

BLUE CROSS®, BLUE SHIELD® and the Cross and Shield Symbols are registered service marks of the Blue Cross and Blue Shield Association, an association of independent Blue Cross and Blue Shield Plans. All other trademarks and service marks contained in this guideline are the property of their respective owners, which are not affiliated with BCBSAZ.

---

### Description:

As required by law, coverage is available under the preventive services benefit for certain newborn screening tests. The newborn screening tests are recommended by the U.S. Department of Health and Human Services Secretary's Discretionary Advisory Committee on Heritable Disorders in Newborns and Children (SACHDNC) to reduce morbidity and mortality in newborns and children having, or at risk for, heritable disorders.

---

## **NEWBORN SCREENING TESTS (cont.)**

### **Criteria:**

➤ The following newborn screening tests are considered **medically necessary**:

1. Endocrine Disorders

- Congenital Adrenal Hyperplasia (CAH)
- Congenital Hypothyroidism (CH)

2. Hemoglobin Disorders

- Sickle Cell Anemia (Hb SS)
- Sickle C Disease
- Sickle Beta Thalassemia (Hb S/βTH)

3. Amino Acid Disorders

- Argininosuccinic Acidemia (ASA)
- Citrullinemia (CIT1)
- Homocystinuria (HCY)
- Maple Syrup Urine Disease (MSUD)
- Phenylketonuria (PKU)
- Tyrosinemia Type 1 (TYR 1)

4. Fatty Acid Oxidation Disorders

- Carnitine Uptake Defect (CUD)
- Medium-chain Acyl-CoA Dehydrogenase Deficiency (MCAD)
- Long-chain 3-OH Acyl-CoA Dehydrogenase Deficiency (LCHAD)
- Trifunctional Protein Deficiency (TFP)
- Very long-chain Acyl-CoA Dehydrogenase Deficiency (VLCAD)



MEDICAL COVERAGE GUIDELINES  
SECTION: LABORATORY

ORIGINAL EFFECTIVE DATE: 08/01/12  
LAST REVIEW DATE: 09/18/18  
LAST CRITERIA REVISION DATE: 09/18/18  
ARCHIVE DATE:

---

## NEWBORN SCREENING TESTS (cont.)

### Criteria: (cont.)

➤ The following newborn screening tests are considered **medically necessary:** (cont.)

#### 5. Organic Acid Disorders

- 3-Hydroxy-3-methylglutaric Aciduria (HMG)
- 3-Methylcrotonyl-CoA Carboxylase Deficiency (3MCC)
- Beta-Ketothiolase Deficiency ( $\beta$ KT)
- Glutaric Acidemia Type 1 (GA-1)
- Isovaleric Acidemia (IVA)
- Methylmalonic Acidemia – cobalamin disorders (Cbl A, B)
- Methylmalonic Acidemia – mutase deficiency (MUT)
- Multiple Carboxylase Deficiency (MCD)
- Propionic Acidemia (PROP)

#### 6. Other Disorders

- Biotinidase Deficiency (BIO)
- Critical congenital heart disease (CCHD)
- Cystic fibrosis (CF)
- Galactosemia (GALT)
- Hearing loss (HEAR)
- Glycogen storage disease type II (GSD II, Pompe)
- Mucopolysaccharidosis Type I (MPS I)
- Spinal Muscular Atrophy due to homozygous deletion of exon 7 in SMN1
- Severe combined immunodeficiency (SCID)
- X-linked Adrenoleukodystrophy (X-ALD)

---

### Resources:

Literature reviewed 09/18/18. We do not include marketing materials, poster boards and non-published literature in our review.

1. Al Mazrouei SK, Moore J, Ahmed F, Mikula EB, Martin GR. Regional implementation of newborn screening for critical congenital heart disease screening in abu dhabi. *Pediatr Cardiol.* Aug 2013;34(6):1299-1306.
2. Arizona Department of Health Services. Arizona Newborn Screening Program Guidelines. Accessed 09/09/2018, 03/02/2018, 02/07/2017, 03/08/2016, 05/14/2015, 07/21/2014, 06/13/2013.
3. Centers for Disease Control (CDC). Screening for Critical Congenital Heart Defects. 07/08/2013.



**MEDICAL COVERAGE GUIDELINES**  
**SECTION: LABORATORY**

**ORIGINAL EFFECTIVE DATE: 08/01/12**  
**LAST REVIEW DATE: 09/18/18**  
**LAST CRITERIA REVISION DATE: 09/18/18**  
**ARCHIVE DATE:**

---

## **NEWBORN SCREENING TESTS (cont.)**

### **Resources:** (cont.)

4. Ewer AK. Review of pulse oximetry screening for critical congenital heart defects in newborn infants. *Curr Opin Cardiol*. Mar 2013;28(2):92-96.
5. Harden BW, Martin GR, Bradshaw EA. False-Negative Pulse Oximetry Screening for Critical Congenital Heart Disease: The Case for Parent Education. *Pediatr Cardiol*. Jul 12 2012.
6. Ma XJ, Huang GY. Neonatal pulse oximetry screening improves detecting of critical congenital heart disease. *Chin Med J (Engl)*. Jul 2013;126(14):2736-2740.
7. Mouldoux JH, Walsh WF. Evaluating the Diagnostic Gap: Statewide Incidence of Undiagnosed Critical Congenital Heart Disease Before Newborn Screening With Pulse Oximetry. *Pediatr Cardiol*. Apr 18 2013.
8. State of Arizona. Report of blood tests; newborn screening program; committee; fee; definitions. *Arizona Revised Statute §36-694*. Accessed 07/21/2014, 06/13/2013.
9. Thangaratinam S, Brown K, Zamora J, Khan KS, Ewer AK. Pulse oximetry screening for critical congenital heart defects in asymptomatic newborn babies: a systematic review and meta-analysis. *Lancet*. Jun 30 2012;379(9835):2459-2464.
10. U.S. Department of Health and Human Services. Recommended Uniform Screening Panel of the Secretary's Discretionary Advisory Committee on Heritable Disorders in Newborns and Children. Accessed 09/09/2018, 03/02/2018, 02/07/2017, 03/09/2016, 04/07/2015, 07/21/2014, 06/13/2013.
11. U.S. Department of Health and Human Services. Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services under the Patient Protection and Affordable Care Act. Accessed 07/21/2014, 06/13/2013



MEDICAL COVERAGE GUIDELINES  
SECTION: LABORATORY

ORIGINAL EFFECTIVE DATE: 08/01/12  
LAST REVIEW DATE: 09/18/18  
LAST CRITERIA REVISION DATE: 09/18/18  
ARCHIVE DATE:

## NEWBORN SCREENING TESTS (cont.)

### Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, [crc@azblue.com](mailto:crc@azblue.com). You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>

### Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe'é atah nilinígíí Blue Cross Blue Shield of Arizona haada yit'éego bina'idííkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yina'idííkidgo beehaz'áanii hólg díí t'áa hazaadk'ehjí háká a'doowołgo bee haz'ą doo baqah ilinígóó. Ata' halne'ígíí kojí' bich'í' hodíilnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

### Arabic:

إن كان لديك أو لدى شخص تساعد أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل بـ 877-475-4799.

