

Pediatric Preventive Screening

Policy Number: AHS – G2042 – Pediatric Preventive Screening	Prior Policy Name and Number, as applicable: G2042 – Preventive Screening in Children and Adolescents
Effective Date: 06/01/2023	

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I. Policy Description

Preventive screening is a healthcare service with the goal of illness prevention and health management. According to the American College of Preventive Medicine (ACPM, 2019), “preventive medicine focuses on the health of individuals, communities, and defined populations. Its goal is to protect, promote, and maintain health and well-being and to prevent disease, disability, and death.”

Pediatric preventive screening guidelines provide evidence-driven guidance for preventive care screenings and well-child visits. Bright Futures is a “national health promotion and prevention initiative, led by the American Academy of Pediatrics and supported by the Maternal and Child Health Bureau, Health Resources and Services Administration (AAP, 2021a).

This policy refers to laboratory-based preventive screening tests performed on individuals newborn through age 18 years, except for newborn screening for genetic disorders. The World Health Organization (WHO) defines an adolescent as any person between the age of 10 and 19 (WHO, 2021).

For guidance on pediatric diabetes screening using a hemoglobin A1c determination, please refer to policy AHS-G2006-Hemoglobin A1c.

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.

- 1) When it follows all applicable federal and state law recommendations, a newborn screening panel **MEETS COVERAGE CRITERIA.**
- 2) For all newborns, screening for hyperbilirubinemia **MEETS COVERAGE CRITERIA.**
- 3) For all newborns, screening for congenital hypothyroidism utilizing serum thyroxine (T4) and/or thyroid-stimulating hormone (TSH) **MEETS COVERAGE CRITERIA.**

- 4) For all newborns, screening for sickle cell disease **MEETS COVERAGE CRITERIA**.
- 5) Blood lead screening **MEETS COVERAGE CRITERIA** for **any** of the following situations:
 - a) For individuals ages 12 months to 2 years.
 - b) For individuals ages 6 months to 6 years who have an increased risk for lead exposure (see Note 1).
- 6) Screening for anemia with hemoglobin or hematocrit determination **MEETS COVERAGE CRITERIA** for **any** of the following situations:
 - a) For all individuals who are 12 months of age.
 - b) For individuals 4 months and older who are at risk for iron deficiency (see Note 2).
- 7) For individuals 1 month of age or older who are at increased risk of contracting tuberculosis (see Note 3), tuberculosis screening **MEETS COVERAGE CRITERIA**.
- 8) Screening for dyslipidemia using a fasting lipid profile **or** a non-fasting non-HDL-C **MEETS COVERAGE CRITERIA** in **any** of the following situations:
 - a) Annually for children and adolescents who are at increased risk due to personal history or family history (see Note 4).
 - b) Once for all children and adolescents during each of the following age periods:
 - i) 9 – 11 years.
 - ii) 17 – 21 years.
- 9) For sexually active adolescents and those at an increased risk for infection (see Note 5), annual screening for chlamydia, gonorrhea, and/or syphilis infection **MEETS COVERAGE CRITERIA**.
- 10) Annual screening for Hepatitis B virus infection **MEETS COVERAGE CRITERIA** in asymptomatic non-pregnant adolescents at high-risk for infections as mentioned below:
 - a) Persons born in geographic regions with HBsAg prevalence of >2 percent
 - b) U.S.-born persons not vaccinated as infants whose parents were born in geographic regions with HBsAg prevalence of >8 percent
 - c) Injection-drug users
 - d) Men who have sex with men
 - e) Persons with elevated ALT/AST of unknown etiology
 - f) Persons with selected medical conditions who require immunosuppressive therapy
 - g) Infants born to HBsAg- positive mothers
 - h) Household contacts and sex partners of HBV-infected persons
 - i) Persons infected with HIV

- j) Multiple sex partners
 - k) On long-term hemodialysis treatment
- 11) For individuals between 11 and 65 years of age, screening for HIV infection **MEETS COVERAGE CRITERIA.**
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NOTES:

Note 1: Lead exposure risk factors for children as defined by the CDC: living or spending time in a house or building built before 1978; growing up in a low-income household; being a recent immigrant, refugee or recently adopted from less developed countries; living or spending time with a person who works with lead or has hobbies that expose them to lead (CDC, 2022b).

Note 2: Iron deficiency risk factors for children as defined by the AAP: history of prematurity or low birth weight; exposure to lead; exclusive breastfeeding beyond 4 months of age without supplemental iron; weaning to whole milk or complementary foods that do not include iron-fortified cereals or foods naturally rich in iron, feeding problems, poor growth, and inadequate nutrition (Baker et al., 2010).

Note 3: TB risk factors for children as defined by the AAP: close contact with a person with or suspected to have infectious tuberculosis; radiographic or clinical findings suggestive of TB; HIV infection or considered at risk for HIV infection; being of foreign birth (especially if born in Asia, Africa or Latin America, countries of the former Soviet Union) or is a refugee, or immigrant; contact with HIV infected, homeless, nursing home residents, institutionalized or incarcerated individuals, illicit drug users or migrant farm workers; having a depressed immune system; living or has lived in a “high risk for tuberculosis” area; participating in significant travel to countries with endemic infections (AAP, 2022; Nolt et al., 2021).

Note 4: Dyslipidemia risk factors for children as defined by the AAP: pediatric patient family history includes family members with CVD or dyslipidemia that are ≤ 55 years of age for men and ≤ 65 years of age for women; pediatric patients who have an unknown family history or other CVD risk factors such as being overweight (BMI $\geq 85^{\text{th}}$ percentile, $< 95^{\text{th}}$ percentile), obesity (BMI $\geq 95^{\text{th}}$ percentile), hypertension (blood pressure $\geq 95^{\text{th}}$ percentile), cigarette smoking, or diabetes mellitus (Daniels et al., 2008).

Note 5: Risk factors as defined by the CDC include: initiating sex early in adolescence; living in detention facilities; receiving services at STD clinics; being involved in commercial sex exploitation or exchanging sex for drugs, money, food, or housing; having multiple sex partners, having sequential sex partnerships of limited duration or concurrent partnerships; failing to use barrier protection consistently and correctly; having lower socioeconomic status, and facing numerous obstacles to accessing healthcare. At-risk individuals also include: males who have sex with males (YMSM); transgender youths; youths with disabilities, substance abuse, or mental health disorders (CDC, 2022a).

III. Table of Terminology

Term	Definition
AACE	American Association of Clinical Endocrinologists
ACE	American College of Endocrinology
AAFP	American Academy of Family Physicians
AAP	American Academy of Pediatrics
ACA	Affordable Care Act
ACPM	American College of Preventive Medicine
ADA	American Diabetes Association
AIDS	Acquired immunodeficiency syndrome
ALT	Alanine transaminase
AST	Aspartate transaminase
CDC	Centers for Disease Control and Prevention
CLIA '88	Clinical Laboratory Improvement Amendments of 1988
CMS	Centers for Medicare and Medicaid
DNA	Deoxyribonucleic acid
EIA	Enzyme immuno assay
ELISA	Enzyme-linked immunosorbent assay
FDA	Food and Drug Administration
G6PD	Glucose 6-phosphate dehydrogenase deficiency
HBsAg	Hepatitis b surface antigen
HBV	Hepatitis B virus
Hct	Hematocrit
HHS	Health and Human Services
HIV	Human immunodeficiency virus
HRSA	Health Resources and Services Administration
LDTs	Laboratory-developed tests
LP(a)	Lipoprotein a
NLA	National Lipid Association
NSMBB	Newborn screening and molecular biology branch
NSQAP	Newborn screening quality assurance program
RNA	Ribonucleic acid
RUSP	Recommended Uniform Screening Panel
TSH	Thyroid stimulating hormone
USPSTF	United States Preventive Services Task Force
WHO	World Health Organization

IV. Scientific Background

The annual “wellness visit” or checkup visit to a primary care provider has been a common component of routine health care for several decades. Providers typically review an individual’s

personal history and family history, perform a physical examination, and run a battery of tests during the annual checkup. The types and number of tests performed can vary widely among providers.

Screening (checking for disease when there are no symptoms) can improve the likelihood of early detection and therefore also prognosis (NCI, 2022). The characteristics of a disease or condition, such as significant effects of an untreated disease, high prevalence in healthy populations, and utility of preclinical detection, can make a condition a good candidate for screening. Newborns and adolescents are more susceptible to certain conditions than adults and, consequently, are recommended for different screenings. For example, infants are typically screened for hyperbilirubinemia, although this condition is not seen as frequently in older children or adults. Schools will often be responsible for the screening of certain conditions, including scoliosis (Kelly, 2020).

Newborn screening is provided to healthy populations to identify newborns that require further testing. Each state handles newborn screening according to predetermined mandates. The United States Secretary of Health and Human Services has established the Recommended Uniform Screening Panel (RUSP) which provides a list of conditions that should be screened, including cystic fibrosis and phenylketonuria. A blood sample is typically taken from the heel of the newborn around the time of hospital discharge (Kemper, 2020). Most of these conditions are identified with tandem mass spectrometry or high pressure liquid chromatography, which are both well-validated (HRSA, 2018).

Screening in children and adolescents is also critical. Some of these screenings may not have apparent benefits for many years or even until adulthood, and the American Academy of Pediatrics (AAP) emphasizes that these preventive screenings have an additive effect (AAP, 2017a). Conditions, such as lead poisoning or significant dyslipidemia, may cause irreversible damage during child development, and as such it is crucial to screen for these conditions. Due to the enormous variation in children and families, the AAP provides many recommendations in the form of a periodicity schedule; this schedule is meant for children “who are receiving competent parenting, have no manifestations of any important health problems, and are growing and developing in a satisfactory fashion.” The AAP notes that developmental, psychosocial, or chronic issues may require additional counseling or treatment visits alongside the preventive care visits (AAP, 2017a).

The Bright Futures initiative was started in 1990 by the Maternal and Child Health Bureau to improve the health of children and prevent disease. The AAP partnered with Bright Futures, and these organizations have now issued joint guidelines and recommendations related to the screening of children and adolescents for common preventable and treatable disorders. The recommendations are age-related and aligned with the standard timing of medical visits for children (AAP, 2019, 2021a).

Clinical Utility and Validity

The AAP has noted a lack of strong evidence to support pediatric preventive screening for numerous conditions. However, the AAP has emphasized that “lack of evidence does not mean a lack of effectiveness” and has ensured that their recommendations have adequately assessed the benefit of screening against potential harm (AAP, 2017a).

The Centers for Disease Control and Prevention (CDC) estimates the number of newborn screenings to be 4 million a year in the United States (CDC, 2019a). The CDC performed a study assessing the number of conditions diagnosed as a result of screening newborns and identified approximately 12,500 diagnoses found due to the newborn screening programs, equaling approximately 1 out of 4000 live births. Severe disorders are identified in approximately 5,000 newborns each year (CDC, 2019a). At the time of the study, the core screening panels consisted of 29 core conditions. The five most commonly diagnosed conditions were (in order): hearing loss, primary congenital hypothyroidism, cystic fibrosis, sickle cell disease, and medium-chain acyl-CoA dehydrogenase deficiency. The CDC estimated congenital hearing loss to occur in one to three live births out of 1000. Finally, the CDC estimated the cost of the newborn screening program to be about \$30 per infant, or \$120 million (CDC, 2012). The CDC has also developed a newborn screening and molecular biology branch (NSMBB) and a newborn screening quality assurance program (NSQAP) that assists in the development of analytical methods to measure substances in dried blood spots. Certified materials for newborn screening tests are also produced by this branch (CDC, 2019b).

V. Guidelines and Recommendations

The American Academy of Pediatrics (AAP) and Bright Futures Recommendations for Preventive Pediatric Health Care

The American Academy of Pediatrics (AAP) (through Bright Futures) recommendations include the following screenings. The Bright Futures/AAP Periodicity Schedule describes the screenings, assessments, physical examinations, procedures, and timing of anticipatory guidance recommended for each age-related visit. Below are the laboratory-related screening recommendations:

- Newborn blood and bilirubin
- Anemia risk assessment at 4 months, test at 12 months, and further risk assessments at each subsequent visit with appropriate action to follow, if positive.
- Lead screening at 6, 9, 12, 18, and 24 months and then once annually from 3-6 years, if indicated
- Tuberculosis screening at 1, 6, 12, and 24 months, and then annually thereafter starting at 3 years old, if indicated
- Dyslipidemia screening at 24 months and then every 2 years starting at 4 years old; AAP also recommends screening at least once between ages 9 and 11 and between 17 and 21. Annual risk assessments starting at age 12 up to age 16 are recommended, with appropriate action to follow, if positive.
- STI/HIV screening annually starting at 11 years old, with at least one HIV screening between 15 and 18 (AAP, 2017b, 2021b).

Many of these recommendations were based on the USPSTF's recommendations (AAP, 2017a).

The AAP has also released a policy statement on targeted testing for lead. The AAP recommends targeted testing for lead in immigrant, refugee, or internationally adopted children at time of arrival (AAP, 2016).

The Advisory Committee on Heritable Disorders in Newborns and Children recommendations are included in the Bright Futures' periodicity table. The committee recommends that every newborn screening program include a Recommended Uniform Screening Panel (RUSP) that screens for 35 core disorders and 26 secondary disorders (RUSP, 2020). Required screenings vary by state.

The core disorders are as follows: Propionic Acidemia, Methylmalonic Acidemia, (methylmalonyl-CoA mutase) Methylmalonic Acidemia, (Cobalamin disorders) Isovaleric Acidemia, 3-Methylcrotonyl-CoA Carboxylase Deficiency, 3-Hydroxy-3-Methylglutaric Aciduria, Holocarboxylase Synthase Deficiency, β -Ketothiolase Deficiency, Glutaric Acidemia Type I, Carnitine Uptake Defect/Carnitine Transport Defect, Medium-chain Acyl-CoA Dehydrogenase Deficiency, Very Long-chain Acyl-CoA Dehydrogenase Deficiency, Long-chain L-3 Hydroxyacyl-CoA Dehydrogenase Deficiency, Trifunctional Protein Deficiency, Argininosuccinic Aciduria, Citrullinemia, Type I, Maple Syrup Urine Disease, Homocystinuria, Classic Phenylketonuria, Tyrosinemia Type I, Primary Congenital Hypothyroidism, Congenital adrenal hyperplasia, S,S Disease (Sickle Cell Anemia), S, β eta-Thalassemia, S,C Disease, Biotinidase Deficiency, Critical Congenital Heart Disease, Cystic Fibrosis, Classic Galactosemia Glycogen Storage Disease Type II (Pompe), Hearing Loss, Severe Combined Immunodeficiencies, Mucopolysaccharidosis Type 1, X-linked Adrenoleukodystrophy, Spinal Muscular Atrophy due to homozygous deletion of exon 7 in *SMN1*.

The secondary disorders are as follows: Methylmalonic acidemia with homocystinuria, Malonic acidemia, Isobutyrylglycinuria, 2-Methylbutyrylglycinuria, 3-Methylglutaconic aciduria, 2-Methyl-3-hydroxybutyric aciduria, Short-chain acyl-CoA dehydrogenase deficiency, Medium/short-chain L-3-hydroxyacylCoA dehydrogenase deficiency, Glutaric acidemia type II, Medium-chain ketoacyl-CoA thiolase deficiency, 2,4 Dienoyl-CoA reductase deficiency, Carnitine palmitoyltransferase type I deficiency, Carnitine palmitoyltransferase type II deficiency, Carnitine acylcarnitine translocase deficiency, Argininemia, Citrullinemia type II, Hypermethioninemia, Benign hyperphenylalaninemia, Biopterin defect in cofactor biosynthesis, Biopterin defect in cofactor regeneration, Tyrosinemia, type II, Tyrosinemia, type III, Various other hemoglobinopathies, Galactoepimerase deficiency, Galactokinase deficiency, T-cell related lymphocyte deficiencies (Children, 2020).

There is also another category set forth by the RUSP—conditions for which newborn screening is not indicated. These include conditions that do not have adequate testing or did not meet other criteria in the RUSP's review. These conditions are as follows: Krabbe disease, Pompe disease, Lysosomal storage diseases, Creatine transport defect, Fabry disease, X-linked adrenoleukodystrophy, Hurler-Scheie disease, Biliary atresia, Smith-Lemli-Opitz syndrome, Congenital disorder of glycosylation type Ib, Fragile X syndrome, Duchenne and Becker muscular dystrophy, Congenital Cytomegalovirus infection, α 1-Antitrypsin deficiency, Carbamylphosphate synthetase deficiency, Adenosine deaminase deficiency, Turner syndrome, Arginine: glycine amidinotransferase deficiency, Neuroblastoma, Diabetes mellitus, insulin dependent, Wilson disease, Guanidinoacetate methyltransferase deficiency, Ornithine transcarbamylase deficiency, Carnitine palmitoyltransferase IB deficiency (muscle), Familial hypercholesterolemia (heterozygote), Congenital Toxoplasmosis, Severe combined immunodeficiency, Neonatal hyperbilirubinemia (Kernicterus), Glucose 6-phosphate dehydrogenase deficiency (G6PD) (HHS, 2020b).

“Secondary” disorders refer to a class of conditions that are “part of the differential diagnosis of a core panel condition.” The core disorders refer to conditions appropriate for newborn screening; they all “have specific and sensitive screening tests, a sufficiently well understood natural history, and available and efficacious treatments.” Although states ultimately decide which conditions to screen for in their newborn screening programs, this list from the Department of Health and Human Services provides some standardization to those programs (HHS, 2018, 2020b).

American Association of Clinical Endocrinologists (AACE) and American College of Endocrinology (ACE)

The 2017 AACE and ACE guidelines for Management of Dyslipidemia and Prevention of Cardiovascular Disease Recommend the following for children:

- “In children at risk for FH (e.g., family history of premature cardiovascular disease or elevated cholesterol), screening should be at 3 years of age, between 9 and 11, and at age 18” (Jellinger et al., 2017).
- “Screen adolescents older than 16 years every 5 years or more frequently if they have ASCVD risk factors, have overweight or obesity, have other elements of the insulin resistance syndrome, or have a family history of premature ASCVD” (Jellinger et al., 2017).

American Diabetes Association (ADA)

The ADA standards of Medical Care in Diabetes document state the following recommendations for children and adolescents’ dyslipidemia testing:

- “Initial lipid testing should be performed when initial glycemic control has been achieved and age is ≥ 2 years. If initial LDL cholesterol is ≤ 100 mg/dL (2.6 mmol/L), subsequent testing should be performed at 9-11 years of age. Initial testing may be done with a nonfasting non-HDL cholesterol level with confirmatory testing with a fasting lipid panel” (ADA,2020).
- “If LDL cholesterol values are within the accepted risk level (<100 mg/Dl [2.6 MMOL/l]), a lipid profile repeated every 3 years is reasonable (ADA, 2020).

United States Preventive Services Task Force (USPSTF)

The USPSTF recommends screening for Hepatitis B virus (HBV) in adolescents and adults who are at an increased risk for infection (Grade B) (USPSTF, 2020b). The USPSTF recommends screening for hepatitis C virus (HCV) infection in adults aged 18 to 79 years (Grade B) (USPSTF, 2020a).

In children and adolescents 20 years or younger, the USPSTF concludes that “the current evidence is insufficient to assess the balance of benefits and harms of screening for lipid disorders” (USPSTF, 2016).

The USPSTF recommends screening for syphilis in adolescents who have ever been sexually active and are at increased risk for syphilis infection. The USPSTF continues to recommend

screening for syphilis in nonpregnant persons who are at increased risk for infection (USPSTF, 2022b).

The USPSTF recommends screening for chlamydia and gonorrhea in all sexually active women ages 24 and under (Grade B) (USPSTF, 2014, 2021).

The USPSTF has stated that there is insufficient evidence to assess the balance of benefits and harms of screening for elevated blood lead levels in asymptomatic children ages 1-5 years (Cantor et al., 2019).

The USPSTF recommends screening adolescents 15 and older for HIV infection. Adolescents under 15 but who are at increased risk should also be screened (Grade A) (Chou et al., 2019; USPSTF, 2019).

The USPSTF has deemed the current evidence insufficient for children ages 6-24 months to be screened for iron deficiency anemia (Siu, 2015).

The USPSTF recognized the importance of screening for hemoglobinopathies in newborns including sickle cell disease, but will not update this 2007 recommendation (USPSTF, 2007).

The USPSTF recognized the importance of screening for congenital hypothyroidism in newborns in 2008, but will not update this recommendation (USPSTF, 2008a).

The USPSTF recognized the importance of screening for phenylketonuria in newborns, but will not update this 2008 recommendation (USPSTF, 2008b).

The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening for primary hypertension in asymptomatic children and adolescents to prevent subsequent cardiovascular disease (Moyer, 2013). A 2020 recommendation statement by the USPSTF confirmed that the current evidence is insufficient to assess the balance of benefits and harms of screening for high blood pressure in children and adolescents (in general) (USPSTF, 2022a).

Centers for Disease Control and Prevention

The CDC acknowledges the Bright Futures and USPSTF recommendations for pediatric preventive screening, including HIV screening (CDC, 2018, 2020a). On May 14, 2021, the CDC updated its blood lead reference value (BLRV) from 5 µg/dL to 3.5 µg/dL in response to a recommendation from the Lead Exposure and Prevention Advisory Committee (LEPAC). The BLRV is a metric used to identify children with blood lead levels that are higher than most (97.5th percentile) other children's levels (CDC, 2021).

With respect to the COVID-19 pandemic, the CDC recommends that “healthcare providers should identify children who have missed well-child visits and/or recommended vaccinations and contact them to schedule in-person appointments, with prioritization of infants, children age < 24 months and school-aged children. Developmental surveillance and early childhood screenings...should continue along with referrals for early intervention services and further evaluation if concerns are identified.” Further, “newborn visits should be done in-person, even during the COVID-19 pandemic, to evaluate feeding and weight gain, check for dehydration and

jaundice, [and] ensure all components of newborn screening were completed with appropriate confirmatory testing and follow-up...” (CDC, 2020b).

The American Academy of Family Physicians (AAFP)

The AAFP guidelines recommend various preventive services for children.

For newborns, the AAFP recommends congenital hypothyroidism screening, hearing loss screening, phenylketonuria screening, and sickle cell disease screening. This is closely aligned with USPSTF guidelines (Lin, 2015).

For sexually active adolescent females, the AAFP recommends gonorrhea and chlamydia infection screening (Lin, 2015). The AAFP supports the USPSTF recommendation for syphilis screening as listed above (AAFP, 2016).

For children and adolescents at high risk of infection, the AAFP recommends HIV and Hepatitis B screening (Lin, 2015).

To address and help rectify low-value care practices, Schefft et al. (2019) published on the inception of a series of “do and don’t” recommendations in the delivery of healthcare for children and adolescents (Schefft et al., 2019). These recommendations include a suggestion for laboratory-based screening:

- “Don't routinely screen for hyperlipidemia in children and adolescents.”

Turner (2018) confirms that the AAFP “generally adheres to USPSTF recommendations” and references several recommendations about screening from the USPSTF and AAP as listed below. The recommendations included below are only those that are within the scope of this medical policy (laboratory-based preventive screening tests):

Screening Recommendations for Children from Birth to 6 Years of Age:

- Dyslipidemia screening by a fasting lipid panel received a grade of “insufficient evidence” by the USPSTF. The AAP recommends “risk-based screening at 2, 4, and 6 years of age (SOR C).”
- Iron deficiency screening by complete blood count received a grade of “insufficient evidence” by the USPSTF. The AAP recommends “screen at 12 months; consider supplements for preterm or exclusively breastfed newborns (SOR C).”
- Lead poisoning screening by measuring lead levels. The USPSTF states that there is “insufficient evidence to recommend screening in children 1 to 5 years of age without increased risk (Grade I).” The AAP recommends “screen[ing] high-risk individuals 6 months to 6 years of age (SOR C)” (Turner, 2018).

National Lipid Association (NLA)

The guidelines list recommendations for “youth” (<20 years old), stating that “Measurement of Lp(a) may be reasonable with:

- Clinically suspected or genetically confirmed FH.
- Individuals with a family history of first-degree relatives with premature ASCVD (<55 y of age in men, 65 y of age in women)
- An unknown cause of ischemic stroke
- A parent or sibling found to have an elevated Lp(a)” (Wilson et al., 2022).

VI. Applicable State and Federal Regulations

Food and Drug Administration (FDA)

The FDA has approved multiple tests for pediatric preventive screening.

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.

Although the HHS has created the RUSP to provide some standardization for each state’s newborn screening programs, the HHS emphasizes that the conditions screened in each program are ultimately decided by the states.

Public Health Service Act (PHS Act)

As per the U.S. Department of Health and Human Services, Section 2713 of the PHS Act “generally requires group health plans and group and individual health insurance issuers that are not grandfathered health plans to provide coverage for recommended preventive services without cost sharing. A complete list of the current recommended preventive services is available at www.healthcare.gov/center/regulations/prevention.html” (HHS, 2020a).

National Association of State Boards of Education (NASBE)

The NASBE provides information about state mandates for school health screening (NASBE, 2022).

Please note that individual states may provide specific guidelines and recommendations for pediatric preventive screening

VII. Applicable CPT/HCPCS Procedure Codes

Procedure codes appearing in medical policy documents are only included as a general reference. This list may not be all inclusive and is subject to updates. In addition, codes listed are not a guarantee of payment.

CPT	Code Description
80061	Lipid panel This panel must include the following: Cholesterol, serum, total (82465) Lipoprotein, direct measurement, high density cholesterol (HDL cholesterol) (83718) Triglycerides (84478)
82247	Bilirubin; total
82248	Bilirubin; direct
82465	Cholesterol, serum or whole blood, total
83655	Lead
83718	Lipoprotein, direct measurement; high density cholesterol (HDL cholesterol)
84439	Thyroxine; free
84443	Thyroid stimulating hormone (TSH)
84478	Triglycerides
85014	Blood count; hematocrit (Hct)
85018	Blood count; hemoglobin (Hgb)
85660	Sickling of RBC, reduction
86480	Tuberculosis test, cell mediated immunity antigen response measurement; gamma interferon
86580	Skin test; tuberculosis, intradermal
86689	Antibody; HTLV or HIV antibody, confirmatory test (eg, Western Blot)
86703	Antibody; HIV-1 and HIV-2, single result
86704	Hepatitis B core antibody (HBcAb); total
86705	Hepatitis B core antibody (HBcAb); IgM antibody
86706	Hepatitis B surface antibody (HBsAb)
86850	Antibody screen, RBC, each serum technique
87340	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; hepatitis B surface antigen (HBsAg)
87341	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; hepatitis B surface antigen (HBsAg) neutralization
87390	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; HIV-1
87391	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; HIV-2
87516	Infectious agent detection by nucleic acid (DNA or RNA); hepatitis B virus, amplified probe technique
87517	Infectious agent detection by nucleic acid (DNA or RNA); hepatitis B virus, quantification

CPT	Code Description
87534	Infectious agent detection by nucleic acid (DNA or RNA); HIV-1, direct probe technique
87535	Infectious agent detection by nucleic acid (DNA or RNA); HIV-1, amplified probe technique, includes reverse transcription when performed
87536	Infectious agent detection by nucleic acid (DNA or RNA); HIV-1, quantification, includes reverse transcription when performed
87537	Infectious agent detection by nucleic acid (DNA or RNA); HIV-2, direct probe technique
87538	Infectious agent detection by nucleic acid (DNA or RNA); HIV-2, amplified probe technique, includes reverse transcription when performed
87539	Infectious agent detection by nucleic acid (DNA or RNA); HIV-2, quantification, includes reverse transcription when performed
87555	Infectious agent detection by nucleic acid (DNA or RNA); Mycobacteria tuberculosis, direct probe technique
87556	Infectious agent detection by nucleic acid (DNA or RNA); Mycobacteria tuberculosis, amplified probe technique
87806	Infectious agent antigen detection by immunoassay with direct optical (ie, visual) observation; HIV-1 antigen(s), with HIV-1 and HIV-2 antibodies
88720	Bilirubin, total, transcutaneous
0257U	Very long chain acyl-coenzyme A (CoA) dehydrogenase (VLCAD), leukocyte enzyme activity, whole blood Proprietary test: Very-Long Chain Acyl-CoA Dehydrogenase (VLCAD) Enzyme Activity Lab/Manufacturer: Children's Hospital Colorado Laboratory
S3620	Newborn metabolic screening panel, includes test kit, postage and the laboratory tests specified by the state for inclusion in this panel (e.g., galactose; hemoglobin, electrophoresis; hydroxyprogesterone, 17-D; phenylalanine (PKU); and thyroxine, total)
S3645	HIV-1 antibody testing of oral mucosal transudate

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VIII. Evidence-based Scientific References

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IX. Revision History

Revision Date	Summary of Changes
01/01/2022	Initial Effective Date
07/19/2022	<p>Updated background, guidelines, and evidence-based scientific references. Literature review did not necessitate any modification to coverage criteria. The following changes were made for clarity:</p> <p>CC5a: remove all “children”: Ages 12 months to 2 years and</p> <p>CC5b: remove “children”: Ages 6 months to 6 years who are at increased risk for lead exposure, as defined by the AAP (poor, those who are recent immigrants, those in older, poorly maintained housing, those who had a sibling or playmate with an elevated blood lead concentration, those who have parents exposed to lead at work, or those who had lived in or visited a structure that might contain deteriorated, damaged, or recently remodeled lead-painted surfaces).</p> <p>CC7: added “with an individual who”: Tuberculosis screening MEETS COVERAGE CRITERIA for children age 1 month and older who are at increased risk: born in a country other than the U.S., Canada, Australia, New Zealand, or Western Europe, traveled (had contact with resident populations) for longer than 1 week to a country with high risk for tuberculosis, has a family member or contact with an individual who had tuberculosis or a positive tuberculin skin test, or is infected with HIV.</p> <p>Removed codes 86701 and 86702</p> <p>Added code 0257u</p> <p>Revised code disclaimer statement</p>
04/04/2023	<p>Updated the background, guidelines and recommendations, and evidence-based scientific references. Literature review did not necessitate any modifications to coverage criteria. The following edits were made for clarity:</p> <p>All CC except CC10 were edited for clarity and consistency.</p> <p>CC12 was removed as a CC and is now a note in the Policy Description to see AHS-G2006 for guidance on Hemoglobin A1c screening.</p> <p>CC5.b., CC6.b., CC7, CC8.a., and CC9 all contained a list of high risk situations- these have all been moved into Notes, resulting in Notes 1-5.</p>

Revision Date	Summary of Changes
	Removed CPT codes 86592, 86593, 86631, 86632, 86780, 87110, 87270, 87320, 87490, 87491, 87590, 87591, 87810, 87850. Committee approved 4/4/2023