

Pediatric Preventive Screening

Policy Number: AHS – G2042 – Pediatric Preventive Screening	Prior Policy Name and Number, as applicable: G2042 – Preventive Screening in Children and Adolescents
Initial Presentation Date: 11/16/2015	
Revision Date: 03/03/2021	

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, 2021).

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).

II. Related Policies

Policy Number	Policy Title
AHS-G2009	Preventive Screening in Adults

III. 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. Newborn screening panel **MEETS COVERAGE CRITERIA** when it follows all applicable federal and state law recommendations.

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2. Screening for hyperbilirubinemia in all newborns **MEETS COVERAGE CRITERIA.**
3. Screening for congenital hypothyroidism in all newborns utilizing serum thyroxine (T4) and/or thyroid-stimulating hormone (TSH) **MEETS COVERAGE CRITERIA.**
4. Screening for sickle cell disease in all newborns **MEETS COVERAGE CRITERIA.**
5. Blood lead screening **MEETS COVERAGE CRITERIA** for children:
 - a. All children ages 12 months to 2 years and
 - b. 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).
6. Screening for anemia with hemoglobin or hematocrit determination **MEETS COVERAGE CRITERIA:**
 - a. For all children 12 months of age, and
 - b. For children 4 months and older if at risk for iron deficiency, 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).
7. 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 had tuberculosis or a positive tuberculin skin test, or is infected with HIV.
8. Screening for dyslipidemia with a fasting lipid profile or a non-fasting non-HDL-C **MEETS COVERAGE CRITERIA:**
 - a. Annually for children and adolescents who are at increased risk due to personal history or family history, as defined by the AAP and Bright Futures criteria (children who consume excessive saturated fats, have elevated blood pressure, have diabetes, are physically inactive, have renal disease, have a body mass index at or above the 85th percentile, have an unobtainable family history, have any factors for coronary artery disease, or have a family history of parents or grandparents who

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have had a stroke or heart problem before age 55 or a parent with elevated blood cholesterol (240 mg/dL or higher) or who is taking cholesterol medication).

- b. Once for all children and adolescents during each of the age periods
 - i. 9 – 11 years and
 - ii. 17 – 21 years
9. Annual screening for Chlamydia, Gonorrhea and Syphilis infection **MEETS COVERAGE CRITERIA** in sexually active adolescents and those at increased risk for infection (men who have sex with men, sex workers, individuals with high risk sexual behavior, persons who exchange sex for drugs, history of other sexually transmitted diseases, individuals in adult correctional facilities).
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. Screening for HIV infection **MEETS COVERAGE CRITERIA** in adolescents and adults, ages 11 to 65 years.
12. For diabetes screening with a hemoglobin A1c determination, please refer to policy AHS-G2006 Hemoglobin A1c.

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IV. Scientific Background

The annual “wellness visit” or checkup visit to a primary care provider has been a common part 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.

Characteristics of a disease, such as significant effects of an untreated disease, high prevalence in healthy populations, and utility of preclinical detection, make a condition a good candidate for screening. Newborns and adolescents are exposed to different 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 of great importance. These tests are given 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. The 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 (HHS, 2018a; HRSA, 2018).

Screening in children or adolescents is also critical. Some of these screenings may not have apparent effects for many years or may even become evident only in 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 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).

Clinical Validity and Utility

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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 amount of conditions diagnosed as a result of screening newborns and identified approximately 12,500 diagnoses found due to the newborn screening programs or 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) which 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 (AAP, 2017b, 2020)

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 screening at 4, 12 months, and then annually thereafter (if indicated)
- Lead screening at 6, 9, 12, 18, 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
- STI/HIV screening annually starting at 11 years old, with at least one HIV screening between 15 and 18 (AAP, 2017b, 2020).

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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 -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, Isobutyrylglucosuria, 2-Methylbutyrylglucosuria, 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

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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, 2020).

“Secondary” disorders refer to a class of disorders that are “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, 2018b).

United States Preventive Services Task Force (USPSTF) (Bibbins-Domingo et al., 2016; Cantor et al., 2019; Chou, Dana, Grusing, & Bougatsos, 2019; USPSTF, 2006, 2007, 2008a, 2008b, 2014, 2016, 2019, 2020)

The USPSTF gives a B recommendation and recommends screening for Hepatitis B virus (HBV) in adolescents and adults who are at an increased risk for infection (USPSTF, 2020).

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 asymptomatic, nonpregnant adults and adolescents who are at increased risk of infection (Bibbins-Domingo et al., 2016).

The USPSTF recommends screening for chlamydia and gonorrhea in women ages 24 and under (USPSTF, 2014).

The USPSTF has stated that there is insufficient evidence to assess the 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 (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).

Centers for Disease Control and Prevention (CDC, 2020)

The CDC acknowledges the Bright Future's and USPSTF recommendations for pediatric preventive screening, including HIV screening (CDC, 2018, 2020).

The American Academy of Family Physicians (AAFP) (AAFP, 2016; Lin, 2015)

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).

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

VI. State and Federal Regulations, as applicable

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. Additionally, 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). As an LDT, the U. S. Food and Drug Administration has not approved or cleared this test; however, FDA clearance or approval is not currently required for clinical use.

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VII. Applicable CPT/HCPCS Procedure Codes

Code Number	Code Description
80061	Lipid Panel
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
86592	Syphilis test, non-treponemal antibody; qualitative (eg, VDRL, RPR, ART)
86593	Syphilis test, non-treponemal antibody; quantitative
86631	Antibody; Chlamydia
86632	Antibody; Chlamydia, IgM
86689	Antibody; HTLV or HIV antibody, confirmatory test (eg, Western Blot)
86701	Antibody; HIV-1
86702	Antibody; HIV-2

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Code Number	Code Description
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)
86780	Antibody; Treponema pallidum
86850	Antibody screen, RBC, each serum technique
87110	Culture, chlamydia, any source
87270	Infectious agent antigen detection by immunofluorescent technique; Chlamydia trachomatis
87320	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)
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],

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Code Number	Code Description
	fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative; HIV-2
87490	Infectious agent detection by nucleic acid (DNA or RNA); Chlamydia trachomatis, direct probe technique
87491	Infectious agent detection by nucleic acid (DNA or RNA); Chlamydia trachomatis, amplified probe technique
87516	Infectious agent detection by nucleic acid (DNA or RNA); hepatitis B, amplified probe technique
87517	Infectious agent detection by nucleic acid (DNA or RNA); hepatitis B virus, quantification
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
87590	Infectious agent detection by nucleic acid (DNA or RNA); Neisseria gonorrhoeae, direct probe technique
87591	Infectious agent detection by nucleic acid (DNA or RNA); Neisseria gonorrhoeae, amplified probe technique

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Code Number	Code Description
87806	Infectious agent antigen detection by immunoassay with direct optical (ie, visual) observation; HIV-1 antigen(s), with HIV-1 and HIV-2 antibodies
87810	Infectious agent antigen detection by immunoassay with direct optical (ie, visual) observation; Chlamydia trachomatis
87850	Infectious agent antigen detection by immunoassay with direct optical (ie, visual) observation; Neisseria gonorrhoeae
88720	Bilirubin, total, transcutaneous
S3620	Newborn metabolic screening panel, includes test kit, postage and laboratory tests specified by the state for inclusion in this panel (e.g., galactose; hemoglobin, electrophoresis; hydroxyprogesterone, 17-D; phenylamine (PKU); and thyroxine, total)
S3645	HIV-1 antibody testing of oral mucosal transudate

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Procedure codes appearing in Medical Policy documents are included only as a general reference tool for each policy. They may not be all-inclusive.

VIII. Evidence-based Scientific References

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