

group or individual health insurance coverage provide coverage without cost-sharing for certain preventive health services. Section 2713(a)(3) describes such services for infants, children, and adolescents as “evidence-informed preventive care and screenings provided for in the comprehensive guidelines supported by the Health Resources and Services Administration.” HHS, along with the Departments of Treasury and Labor, issued an Interim Final Rule on July 19, 2010 (75 FR 41726–41760) that identified two specific resources as the comprehensive guidelines supported by HRSA for infants, children, and adolescents to be covered by insurance without cost sharing by non-grandfathered group health plans and health insurance issuers: (1) The Bright Futures Periodicity Schedule and (2) the Recommended Uniform Screening Panel of the Advisory Committee on Heritable Disorders in Newborns and Children. The Interim Final Rule provided that a future change to these comprehensive guidelines is considered to be issued for purposes of Section 2713 on the date on which it is accepted by the HRSA Administrator or, if applicable, adopted by the Secretary of HHS.

A public comment period was announced and occurred from September 13, 2021, through October 13, 2021 (86 FR 50894, September 13, 2021),¹ to allow public comment on the proposed recommended updates affecting clinical practice and health insurance coverage requirements. A total of 27 respondents gave 57 comments during the public comment period. The Bright Futures grantee, the American Academy of Pediatrics, received and considered the public comments. The annual report (Tab A) provides a description of the comments, including a detailed tabulation of each comment.

On December 30, 2021, the HRSA Administrator accepted the American Academy of Pediatrics’ recommended several updates to the Bright Futures Periodicity Schedule. The Bright Futures recommendations included recommended clinical practice updates, along with revisions to the footnotes on the Bright Futures Periodicity Schedule that do not require changes to clinical practice or health insurance coverage. The updates to the Bright Futures Periodicity Schedule are: (1) A new category for sudden cardiac arrest and sudden cardiac death risk assessment, (2) a new category for hepatitis B virus

infection risk assessment, (3) addition of suicide risk as an element of universal depression screening for children ages 12–21, and (4) updated category title from “Psychosocial/Behavioral Assessment” to “Behavioral/Social/Emotional Screening,” with no revision to the ages in which the screening occurs (newborn to 21 years). Finally, two clarifying references related to dental fluoride varnish and fluoride supplementation have been added with no associated recommended changes to clinical practice. In light of these updates, all non-grandfathered group health plans and health insurance issuers offering group or individual health insurance coverage must cover without cost-sharing the services and screenings listed on the updated Bright Futures Periodicity Schedule for plan years (in the individual market, policy years) that begin in 2023, which can be accessed at the following link: <https://mchb.hrsa.gov/maternal-child-health-topics/child-health/bright-futures.html>.

Diana Espinosa,

Acting Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Update to the Women’s Preventive Services Guidelines

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: On December 30, 2021, HRSA approved updates to the HRSA-supported Women’s Preventive Services Guidelines (Guidelines) that address health needs specific to women. The Guidelines are based on clinical recommendations from the Women’s Preventive Services Initiative (WPSI), a coalition of experts and health professional organizations convened by the American College of Obstetricians and Gynecologist (ACOG) under a cooperative agreement awarded by HRSA. Under the Public Health Service Act and pertinent regulations, preventive care and screenings for women provided for in comprehensive guidelines supported by HRSA are required to be covered without cost sharing by group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage. This 2021

update adds one additional service, Preventing Obesity in Midlife Women, and revises five services: Breastfeeding Services and Supplies, Contraception, Screening for Human Immunodeficiency Virus Infection, Counseling for Sexually Transmitted Infections, and Well-Woman Preventive Visits. This notice serves as an announcement of the decision to update the Guidelines as further described below. Please see <https://www.hrsa.gov/womens-guidelines/index.html> for additional information.

FOR FURTHER INFORMATION CONTACT:

Kimberly Sherman, HRSA, Maternal and Child Health Bureau, telephone (301) 443–8283, email: wellwomancare@hrsa.gov.

SUPPLEMENTARY INFORMATION: The updated 2021 HRSA-supported Women’s Preventive Services Guidelines, along with information related to their development and implementation, are available at <https://www.hrsa.gov/womens-guidelines/index.html>. A summary of information regarding the updates to the comprehensive guidelines supported by HRSA on December 30, 2021, is set out below.

Women’s Preventive Services Guidelines

The first HRSA-supported Guidelines, based on recommendations of the Institute of Medicine, were established in 2011. The Guidelines were subsequently updated following review and recommendations by the ACOG under the WPSI cooperative agreement, awarded by HRSA in 2016. The purpose of WPSI is to improve adult women’s health across the lifespan by engaging a coalition of experts and health professional organizations to recommend updates to the HRSA-supported Guidelines. Following such review and recommendations, HRSA decides whether or not to support, in whole or in part, the recommended updates to the Guidelines. In March 2021, HRSA awarded a subsequent cooperative agreement to ACOG to provide recommendations as appropriate over a 5-year period to update the HRSA-supported Guidelines. Under the cooperative agreement, ACOG, through the WPSI, engages in a process to consider and review new and existing Guidelines developed by a multidisciplinary group of women’s health experts and professional organizations.

Under section 2713 of the Public Health Service Act, 42 U.S.C. 300gg–13, group health plans and issuers of non-grandfathered group and individual

¹ See <https://www.federalregister.gov/documents/2021/09/13/2021-19630/opportunity-for-comments-on-proposed-updates-to-the-bright-futures-periodicity-schedule-as-part-of>.

health insurance coverage are required to cover specified preventive services without a copayment, coinsurance, deductible, or other cost sharing, including preventive care and screenings for women as provided for in comprehensive guidelines supported by HRSA for this purpose. Private health insurance companies must provide this coverage without cost-sharing in plan years (in the individual market, policy years) beginning on or after the date that is one year after the date the recommendation or guideline is issued. A change to the Guidelines is considered to be issued on the date on which it is accepted by the HRSA Administrator.

Summary of the 2021 Updates Recommended by WPSI and Approved by HRSA

Breastfeeding Services and Supplies

WPSI recommends comprehensive lactation support services (including consultation, counseling, education by clinicians and peer support services, and breastfeeding equipment and supplies) during the antenatal, perinatal, and postpartum periods to optimize the successful initiation and maintenance of breastfeeding.

Breastfeeding equipment and supplies include, but are not limited to, double electric breast pumps (including pump parts and maintenance) and breast milk storage supplies. Access to double electric pumps should be a priority to optimize breastfeeding and should not be predicated on prior failure of a manual pump. Breastfeeding equipment may also include equipment and supplies as clinically indicated to support dyads with breastfeeding difficulties and those who need additional services.

Contraception

WPSI recommends that adolescent and adult women have access to the full range of contraceptives and contraceptive care to prevent unintended pregnancies and improve health outcomes. Contraceptive care includes screening, education, counseling, and provision of contraceptives (including in the immediate postpartum period). Contraceptive care also includes follow-up care (e.g., management, evaluation, and changes, including the removal, continuation, and discontinuation of contraceptives).

WPSI recommends that the full range of U.S. Food and Drug Administration (FDA)-approved, -granted, or -cleared contraceptives, effective family planning practices, and sterilization

procedures be available as part of contraceptive care. The full range of contraceptives currently includes those listed in the FDA's Birth Control Guide:¹ (1) Sterilization surgery for women, (2) implantable rods, (3) copper intrauterine devices, (4) intrauterine devices with progestin (all durations and doses), (5) injectable contraceptives, (6) oral contraceptives (combined pill), (7) oral contraceptives (progestin only), (8) oral contraceptives (extended or continuous use), (9) the contraceptive patch, (10) vaginal contraceptive rings, (11) diaphragms, (12) contraceptive sponges, (13) cervical caps, (14) condoms, (15) spermicides, (16) emergency contraception (levonorgestrel), and (17) emergency contraception (ulipristal acetate); and any additional contraceptives approved, granted, or cleared by the FDA.

Screening for HIV Infection

WPSI recommends all adolescent and adult women, ages 15 and older, receive a screening test for human immunodeficiency virus (HIV) at least once during their lifetime. Earlier or additional screening should be based on risk, and rescreening annually or more often may be appropriate beginning at age 13 for adolescent and adult women with an increased risk of HIV infection.

WPSI recommends risk assessment and prevention education for HIV infection beginning at age 13 and continuing as determined by risk.

A screening test for HIV is recommended for all pregnant women upon initiation of prenatal care with rescreening during pregnancy based on risk factors. Rapid HIV testing is recommended for pregnant women who present in labor with an undocumented HIV status.

Counseling for Sexually Transmitted Infections

WPSI recommends behavioral counseling by a health care clinician or other appropriately trained individual for sexually active adolescent and adult women at an increased risk for sexually transmitted infections (STIs).

WPSI recommends that clinicians review a woman's sexual history and risk factors to identify those at increased risk for STIs. Risk factors include, but are not limited to, age younger than 25 years, a recent history of an STI, a new sex partner, multiple partners, a partner with concurrent partners, a partner with an STI, and a lack of or inconsistent

condom use. For those without identified risk factors, counseling to reduce the risk of STIs should be considered on an individual basis as determined by clinical judgment.

Well-Woman Preventive Visits

WPSI recommends that women receive at least one preventive care visit per year beginning in adolescence and continuing across the lifespan to ensure the provision of all recommended preventive services. The primary purpose of well-woman visits is the delivery and coordination of recommended preventive services as determined by age and risk factors. These services may be completed at a single visit or as part of a series of visits that take place over time to obtain all necessary services depending on a woman's age, health status, reproductive health needs, pregnancy status, and risk factors. Well-women visits also include pre-pregnancy, prenatal, postpartum, and interpregnancy visits.

Preventing Obesity in Midlife Women

WPSI recommends counseling midlife women aged 40 to 60 years with normal or overweight body mass index (BMI) (18.5–29.9 kg/m²) to maintain weight or limit weight gain to prevent obesity. Counseling may include individualized discussion of healthy eating and physical activity.

Diana Espinosa,

Acting Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Request for Public Comment: 30 Day Notice for Extension of Fast Track Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery: IHS Customer Service Satisfaction and Similar Surveys

AGENCY: Indian Health Service, HHS.

ACTION: Notice and request for comments. Request for extension of approval.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Indian Health Service (IHS) invites the general public to take this opportunity to comment on the information collection Office of Management and Budget (OMB) Control Number 0917–0036, “Generic Clearance for the

¹ This refers to FDA's Birth Control Guide (<https://www.fda.gov/media/150299/download>) as posted on December 22, 2021 with the exception of sterilization surgery for men, which is beyond the scope of the WPSI.