ASHA
American
Speech-Language-Hearing
Association

July 2, 2024

Diane Gore
President & CEO
BCBS Wyoming
4000 House Ave
Cheyenne, WY 82001

Re: Blue Cross Blue Shield Wyoming Prior Authorization on Hearing Aid Services Federal Employee Program

Dear President Gore:

On behalf of the American Speech-Language-Hearing Association (ASHA), I write to respectfully request an update to the prior authorization requirements for the Federal Employee Program (FEP) plans outlined in the Blue Cross Blue Shield Wyoming (BCBSWY) *Prior Authorization on Hearing Aids Services*.[1]

ASHA is the national professional, scientific, and credentialing association for 234,000 members, certificate holders, and affiliates who are audiologists; speech-language pathologists (SLPs); speech, language, and hearing scientists; audiology and speech-language pathology assistants; and students. ASHA represents over 14,500 audiologists nationwide. Some audiologists report that they continue to experience denials for medically necessary hearing aids for BCBSWY FEP beneficiaries.

Clarification of 510(k) Exemption for Air-Conduction Hearing Aids

The BCBSWY prior authorization process for hearing aids requires authorizations to include a 510(k) number for approval.[2] The U.S. Food and Drug Administration (FDA) regulations indicate that both legacy non-wireless air-conduction hearing aid devices and wireless air-conduction hearing aid devices are exempt from premarket notification procedures as outlined in sections 21CFR874.3300 and 21CFR874.3305, respectively.[3,4] Therefore, they do not receive 510(k) numbers. The regulations state that an "Air-conduction hearing aid… is exempt from premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 874.9" and "The wireless air-conduction hearing aid is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 874.9."[5,6] Therefore, **ASHA respectfully requests that BCBSWY remove its requirement for a 510(k) number from the hearing aid authorization process.**

Authorization Requirements for Air-Conduction Hearing Aids

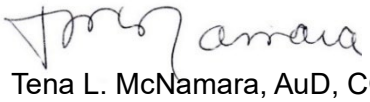
All air-conduction hearing aids on the market should be registered with the FDA. Some manufacturers register parts of the device while others register the entire device. BCBSWY can verify hearing aid registration through the FDA's website—Establishment Registration & Device Listing (fda.gov). However, this listing can be difficult for providers to navigate. Therefore, **ASHA encourages BCBSWY to simplify the prior authorization process by removing any requirement related to verifying FDA registration**.

For example, BCBS Tennessee (BCBST) only requires audiologists to submit the name of the hearing aid being considered for purchase, testing results, and a copy of the prescription/order

for authorization.[7] BCBST's requirement reflects common industry practice, which is to list the name and model of the hearing aid and the name of the manufacturer on an authorization request. **To help address denials for medically necessary hearing aids, ASHA recommends BCBSWY follow the common practice of identifying the hearing aid being considered for purchase and submitting the prescription/order from the audiologist.**

Thank you for your time and attention to this matter. ASHA stands ready to assist your office as you consider our requests. We look forward to ongoing collaboration to ensure BCBSWY FEP beneficiaries receive appropriate access to medically necessary hearing care. If you or your staff have any questions, please contact Meghan Ryan, MSL, ASHA's director of health care policy for private health plans, at mryan@asha.org.

Sincerely,



Tena L. McNamara, AuD, CCC-A/SLP
2024 ASHA President

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[1] Blue Cross Blue Shield of Wyoming. *Prior Authorization on Hearing Aids Services*. (2024, March 15). https://www.bcbswy.com/provider_updates/prior-authorization-on-hearing-aids-services/.
[2] ibid.
[3] U.S. Food and Drug Administration. *21CFR874.9*. (2024, March 22). https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=874.9.
[4] U.S. Food and Drug Administration. *Medical Device Exemptions 510(k) and GMP Requirements, Class II Devices*. Final order. (2018). *Federal Register*, *83*(108), 25910–25915. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/315.cfm?GMPPart=874#start.
[5] U.S. Food and Drug Administration. *21CFR874.3300(b)*. (2024, March 22). https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=874.3300
[6] U.S. Food and Drug Administration. *21CFR874.3305(c)*. (2024, March 22). https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=874.3305.
[7] Blue Cross Blue Shield. *Federal Employee Program Hearing Aid Prior Approval Request Form*. Retrieved June 26, 2024 from https://www.bcbst.com/providers/forms/FEP_Hearing_Aid_Prior_Approval_Request_Form.pdf.