# Neurofeedback/Biofeedback For Behavioral And Substance Use Disorders

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## Introduction & Instructions for Use

### Introduction

Behavioral Clinical Policies are a set of objective and evidence-based behavioral health criteria used by medical necessity plans to standardize coverage determinations, promote evidence-based practices, and support members' recovery, resiliency, and wellbeing for behavioral health benefit plans that are managed by Optum®.

### Instructions for Use

This guideline is used to make coverage determinations as well as to inform discussions about evidence-based practices and discharge planning for behavioral health benefit plans managed by Optum. When deciding coverage, the member's specific benefits must be referenced.

All reviewers must first identify member eligibility, the member-specific benefit plan coverage, and any federal or state regulatory requirements that supersede the member's benefits prior to using this guideline. In the event that the requested service or procedure is limited or excluded from the benefit, is defined differently or there is otherwise a conflict between this guideline and the member's specific benefit, the member's specific benefit supersedes this guideline. Other clinical criteria may

apply. Optum reserves the right, in its sole discretion, to modify its clinical criteria as necessary using the process described in Clinical Criteria. This guideline is provided for informational purposes. It does not constitute medical advice.

Optum may also use tools developed by third parties that are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Optum may develop clinical criteria or adopt externally-developed clinical criteria that supersede this guideline when required to do so by contract or regulation.

## Benefit Considerations

Before using this policy, please check the member-specific benefit plan document and any federal or state mandates, if applicable.

## Description of Service

**Neurofeedback/biofeedback therapy** is a non-invasive technique that uses real-time physical sign monitors, such as electroencephalographs (EEGs), heart-rate variability/respiratory sinus arrhythmia (HRV/RSA), magnetic encephalography (MEG), and functional real-time functional magnetic resonance imaging (rtfMRI). These modalities provide feedback to individuals on how to control physiologic functions and mental states. The real-time feedback such as the individuals' EEG pattern and other physiological processes allows the individual to correct and enhance a mental and behavioral strategy for symptom improvement (Trambaiolli et al., 2021).

## Coverage Rationale

### Neurofeedback or biofeedback (with or without EEG guidance) is unproven and not medically necessary for treating individuals with any behavioral or substance use disorder, including but not limited to:

- Attention-deficit/hyperactivity disorder (ADHD)
- Depression
- Anxiety
- Obsessive-compulsive disorder
- Post-traumatic stress disorder
- Alcohol/drug abuse
- Autism spectrum disorder

The reviewed evidence, including randomized controlled trials and systematic reviews, does not clearly demonstrate a treatment effect of neurofeedback/biofeedback on behavioral or substance use disorders. Many of these reviewed studies contain a number of significant limitations. Additionally, there is a lack of well-designed clinical trials with sufficient sample sizes, randomization, and blinding demonstrating the effectiveness of neurofeedback/biofeedback in the treatment of behavioral and substance use disorders.

## Systematic Reviews and Meta-Analyses

### Attention-Deficit/Hyperactivity Disorder (ADHD)

An UptoDate review by Krull and Chan (2023) states that randomized controlled trials regarding neurofeedback as a treatment for children diagnosed with ADHD have had varying results with numerous limitations and is not recommended as a treatment.

Lam et al. (2022) performed a double-blind, sham-controlled randomized trial examining the efficacy of fMRI neurofeedback on clinical and cognitive measures in children diagnosed with ADHD. Participants were 88 boys ages 10-18 years old diagnosed with ADHD. Participants prescribed stimulant medications were instructed to omit the medication 24 hours before each assessment and could remain on the medication throughout the study. Participants were block-randomized in a 1:1 ratio to an active (n=44) or sham (n=44) intervention group, stratified by medication status (nonmedicated or on stable ADHD medication) and by age group (under or over 14 years 6 months). Participants had 7 visits available; visit 1 for screening and baseline assessment, visits 2-5 for fMRI-NF interventions, and visits 6 and 7 for posttreatment and 6-month follow-up assessments. The intervention comprised 15 active fMRI-NF runs over 1 hour scan sessions; the sham intervention group experienced duplicate procedures but received sham neurofeedback. The primary outcome was measured via the parent-rated ADHD Rating Scale (ADHD-RS) at the posttreatment assessment. Results showed no significant effects for group-by-time interaction, or for group effect on ADHD-RS total scores, as primary posttreatment or secondary 6-month follow-up outcomes. Time effect showed significantly increasing ADHD-RS scores from posttreatment assessment to follow-up assessment ($F=8.44$, $df=1, 82.7$, $p=0.005$). Within-group findings were significantly reduced scores for both groups, compared to baseline, at the posttreatment (p values <0.001) and follow-up (p values <0.009) assessments. Although there was no improvement in ADHD-RS total scores or other clinical and cognitive measures, the sham intervention group showed decreased irritable mood and improved motor inhibition at the posttreatment assessment. There were no side effects or adverse events reported. A limitation noted was that approximately 65% of participants were current medication users, which could taint neurofeedback-related clinical or cognitive effects; future research with replication in a medication-naive study would clarify this. In addition, the researchers state that future studies investigating if different fMRI target regions produce improved cognitive outcomes. Lastly, optimal and standardized protocols for fMRI-NF in ADHD are needed.

Lin et al. (2022) conducted a systematic review and meta-analysis on the additive effects of EEG neurofeedback on medications for ADHD. The meta-analysis included five RCTs with 305 participants diagnosed with ADHD, ages 8 – 11 years old, the median number of neurofeedback treatment sessions was 30 (range: 16–40 weeks). All included trials that utilized theta/beta ratio EEG-NF protocols. There was a lack of blinding in the majority of included studies. The results for the combined approach was not superior to medication alone in the therapeutic effects on the symptoms of hyperactivity/impulsivity from parents' observation, (Hedges' g = 0.1714, 95% CI [− 0.0544 - 0.3971], p = 0.1368, I2 =3.1%). Findings for combining EEG-NF with medications showed no additional therapeutic benefit compared to medication alone (Hedges' g = 0.1201, 95% CI [− 0.3531 - 0.5933], p = 0.6189, I2 =58.6%). Durability results at the median follow-up of 12 weeks showed additive effects of EEG-NF on medications from parents' observations of ADHD symptoms of hyperactivity and impulsivity (Hedges' g = 0.2898, 95%CI [0.0238 - 0.5557]) and inattention symptoms (Hedges' g = 0.3274, 95%CI [0.0493 - 0.6055]). Results showed additive effects lacked durability at six months after EEG-NF intervention (Hedges' g = 0.4807, 95% CI [− 0.2430 - 1.2044], p = 0.1930, I2 = 83.2%). These results support additive benefits of combining EEG-NF with medications compared to medication alone in treating global symptoms and symptoms of inattention in individuals diagnosed with ADHD. The authors note that future trials including participants of diverse demographic backgrounds while using different NF protocols are required to clarify the efficacy of combining EEG-NF with medications in clinical practice.

Lambez et al. (2020) performed a meta-analysis on 18 studies published between 1980 and 2017 regarding the neuropsychological effects of non-pharmacological interventions for ADHD. The interventions within the studies were categorized into four categories: neurofeedback, cognitive-behavioral therapy, cognitive training, and physical exercises. The findings revealed that all interventions demonstrated homogeneous and significant results; neurofeedback showed a moderate effect size of 0.61 (df=5, 95% CIL= −3.77, 4.82). The authors report an overall positive effect of psychological interventions on ADHD cognitive symptomology; this analysis supports the inclusion of non-pharmacological interventions in combination with the pharmacological treatments. The authors acknowledge limitations of this meta-analysis as a small number of studies met the strict inclusion criteria; the majority of studies included mixed groups of participants who were taking stimulant medication during the intervention and testing period; the notable results found in this study are limited to laboratory tasks. There were

numerous quality intervention studies that were not included in this analysis due to their lack of computerized or written neuropsychological tests. The authors conclude that further research should focus on comparing randomized clinical trials while differentiating between medicated and nonmedicated participants.

The Emergency Care Research Institute (ECRI) published a health technology assessment (2020) on neurofeedback (NF) for treating ADHD in children and adolescents. The report examined evidence from 3 meta-analyses that were considered low quality and 3 additional randomized controlled trials; the results indicated that NF is less effective than pharmacotherapy and behavioral therapy in treating ADHD symptoms. Limitations among the studies include use of different NF protocols, varied outcome assessment methods, and small patient groups with different ages. Clinical guidelines from the Canadian ADHD Resource Alliance (2020), the American Academy of Pediatrics (2019), and the Canadian Paediatric Society (2018) state that there is insufficient data to recommend NF for the treatment of ADHD. Future research is required with larger RCTs using standardized NF protocols to assess safety and effectiveness.

Van Doren et al. (2019) conducted a systematic review and meta-analysis to evaluate neurofeedback (NF) in children with ADHD. The review investigated effects of NF after treatment and during 2–12 months post-treatment follow up period, in which no additional neurofeedback sessions or booster sessions were performed. A total of ten studies met inclusion criteria with 10 studies in the NF arm (n = 256) and 9 studies in the control arm (n = 250). The authors concluded that compared to non-active control treatments, NF appears to have more durable treatment effects, for at least 6 months following treatment. The authors indicated that carefully designed RCTs with longer follow-up time periods are needed before definite treatment recommendations can be provided.

Razoki (2018) performed a systematic review aimed to evaluate the efficacy of neurofeedback (NF) compared to stimulant medication in treating children and adolescents with ADHD. The review examined 8 randomized controlled trials that compared an NF condition, either alone or combined with medication. The age of participants ranged from 6-24 years across the 8 studies. The number of NF (theta/beta or theta/SMR) sessions ranged from 20 to 40, and the duration per session ranged from 25 to 50 minutes across the studies. The sample sizes were from n=32 to n=130. Results revealed that when only trials are considered that include probably blinded ratings or those that are sham-NF or semi-active controlled, or those that utilized optimally titration procedures, the findings do not support theta/beta NF as a standalone treatment for children or adolescents with ADHD. Nevertheless, an additive treatment effect of NF was observed on top of stimulants and theta/beta NF was able to decrease medication dosages, and both results were maintained at 6-month follow-up. The authors concluded that the role of NF in treating children diagnosed with ADHD should be considered as complementary in a multimodal treatment approach, individualized to the child, and may be considered a viable option to stimulants for a specific group of patients. Future research should further explore the possibility of NF reducing medication dosages. In addition, future research should prioritize which particular group of patients that may benefit from NF treatment.

## Other Behavioral Disorders

Patil et al. (2023) completed a 12-study systematic review on EEG-based neurofeedback to treat depression. The 12 studies were categorized into two groups based on the NF protocols most commonly used to treat depression symptoms: (1) alpha-asymmetry (ALAY) and (2) high-beta down-training NF protocols. Participants were adults (n=352) diagnosed with MDD or treatment-resistant depression. The overall findings suggest that individuals diagnosed with depression showed notable clinical, cognition, and neural improvements with EEG-NF training. Comparisons of the protocols among the studies revealed superior behavioral and clinical outcomes for high-beta down-training compared to the ALAY protocol. The number of sessions across the studies ranged from 8 – 30 sessions, with duration of sessions ranging from 5 – 12 weeks. Due to the low cost and low risk of adverse effects, the authors recommend exploring EEG-NF as an augmentation tool for individuals being treated with anti-depressants that remain symptomatic. Limitations include minimal studies that have compared participants diagnosed with depression to a healthy control group, variation of protocols, small sample sizes without blinding, and lack of follow-up data. The authors conclude that future research is needed with robust clinical design and larger sample sizes to establish efficacy of EEG-NF for the treatment of depression.

Hong and Park (2022) conducted a systematic review and meta-analysis of neurofeedback (NF) training for post-traumatic stress disorder (PTSD) symptoms to investigate the effects of real-time functional magnetic resonance imaging (fMRI-NFT) and electroencephalogram-based neuro-feedback training (EEG-NFT). Seven studies met the inclusion criteria for the systematic review and meta-analysis. Various NF protocols exist; 3 of the studies used fMRI-NFT and 4 used EEG-NFT; all studies included adult participants (n=114) diagnosed with PTSD. Symptoms were measured as the primary outcomes in all studies, utilizing the

following assessment tools: Clinician-Administered PTSD Scale (CAPS), PTSD Checklist-Military Version (PCL-M), PTSD Diagnostic and Statistical Manual of Mental Disorders Checklist-5th edition (PCL-5), the Davidson Trauma Scale (DTS), the Montgomery–Asberg Depression Rating Scale (MADRS), Beck Depression Inventory (BDI), Hamilton Anxiety Scale (HAM-A), Hamilton Depression Rating Scale (HDRS), Beck Anxiety Inventory (BAI), Impact of the Event Scale-revised (IESR), and Inventory of Altered Self-Capacities (IASC). The findings revealed that EEG-based neuro-feedback training was more beneficial in training PTSD symptoms than fMRI-NFT. A significant result was obtained from EEG-NFT (4 studies, Hedges' g= -1.132, 95% CI: -2.061 to -0.203, $p < 0.05$). A non-significant result was found for fMRI-NFT (3 studies, Hedges' g = -0.368, 95% CI: -0.851 to 0.115, $p < 0.05$) showed low heterogeneity ($Q = 0.156$, $p = 0.925$, $I2 = 0.000$), and the effect size was not significant for PTSD symptoms. Additionally, the methods were also shown to be valid for evaluating clinical PTSD diagnoses with significant results of Hedges' g = -0.658, 95% CI: -0.983 to -0.333, $p < 0.05$). The authors note that future research is needed to establish a gold standard protocol for the EEG-based neuro-feedback training (EEG-NFT) method for treating individuals with PTSD symptoms.

Alvarez et al. (2021) conducted a meta-analyses of 22 clinical studies regarding the efficacy of biofeedback/neurofeedback in the treatment of depression and depressive symptoms. Studies included had either an established diagnosis of depression using a standardized diagnostic tool or participants presented with increased depressive symptoms. In the first group of studies for participants with MDD, the between group analyses, comparing NF to control groups, produced an effect size of Hedges' g = 0.717 and p=0.0121, while the within group analysis of sole NF yielded an effect size of Hedges' g = 1.050 and p=0.001. In the second group of studies for participants with depressive symptoms, a small but significant effect between groups was found of Hedges' g = 0.303 and p=0.003 in support of bio- and neurofeedback versus control groups. Moderator analyses revealed that treatment efficacy was not moderated by any of the sociodemographic and clinical variables. The results revealed biofeedback and neurofeedback are a promising technique associated with a reduction in self-reported depression. The authors note limitations among the studies such as lack of robust clinical design, unclear risk of bias, small sample sizes, heterogeneity of NF protocols, and lack of follow-up assessments. Future rigorous randomized controlled trials are needed to establish clear efficacy and durability.

A systematic review conducted by Trambaiolli and colleagues (2021) examined neurofeedback training efficacy in major depressive disorder, in addition to study quality and reporting practices. Initially, 585 studies were screened for inclusion. Criteria for the 24 selected studies consisted of adults 18 years and older with a current, formal diagnosis of depression. Results among the EEG fMRI studies showed statistically and clinically within group (sole NF) improvements of clinical measures between 6% and 73%. The between group (NF vs. control groups) comparisons showed less significant changes ranging from -7% to 52%. While most of the reviewed studies show positive outcomes with NF compared to control group(s), data from RCTs regarding specific therapeutic effects of NF in depression remains small; future RCTs will require larger samples. The researchers stated that most of these studies did not adhere to stringent study quality or reporting practices in addition to being outdated in following the current best practice standards for study design and reporting. Some of the primary issues addressed by the researchers include heterogeneity of NF protocols, control conditions, lack of blinding, lack of randomization, small sample sizes, and lack of follow-up. The authors acknowledge that these limitations are a barrier to determining clinical efficacy and conclude with recommendations for future research that will identify therapeutic efficacy of NF in depression treatment.

Steingrimsson et al. (2020) performed a systematic review and meta-analysis on electroencephalography-based neurofeedback (EEG-NF) as treatment for post-traumatic stress disorder (PTSD). Four studies were included with 123 adult participants at least 18 years old and diagnosed with PTSD. Outcomes examined were the EEG-NF intervention compared to sham EEG-NF, other treatments such as psychotherapy and medications, or no treatment. Among the 4 studies the number of total EEG-NF sessions ranged from 20-30 with varied frequency. A notable result was found in the EEG-NF versus no treatment category, 3 RCTs (n=92), the EEG-NF group reported a decrease in PTSD symptoms (Mean difference, -2.30; 95% CI, -4.27 to - 0.24), $p = 0.03$. The authors discuss numerous limitations with the 3 RCTs such as small sample size, vague blinding and randomization techniques, and different scales used to measure PTSD symptoms. Follow-up was done in 1 study, 4 weeks after treatment completion with findings of a reduction of PTSD symptoms of 34% on the Davidson Trauma Scale after EEG-NF versus 8% in the control group ($p < 0.001$). Lack of durability measures is noted in 3 of the 4 studies. The authors conclude that future trials should include quality research design, larger sample sizes with less heterogeneity in treatment protocols.

Ferreira et al. (2019) conducted a systematic review and meta-analysis to assess the therapeutic efficacy of biofeedback in obsessive-compulsive and related disorders (OCD&RD) category (body dysmorphic, hoarding, trichotillomania, and excoriation disorders). Ten studies containing 102 OCD participants (three randomized controlled trials) mostly applying neurofeedback

(one publication used thermal biofeedback) were included in the review. Five neurofeedback studies were selected for meta-analysis (89 patients; two randomized controlled trials). The authors found a beneficial effect of neurofeedback for OCD symptoms, but also found critical limitations on methodology, high heterogeneity among studies, and a reporting bias. Future research following high-quality guidelines with well-designed methodology are needed to address the efficacy of biofeedback approaches for OCD&RD.

Imperatori et al. (2018) conducted a systematic review to evaluate the effectiveness of biofeedback and neurofeedback for eating disorders (EDs) and EDs-related symptoms. Thirteen studies were included in the review. Neurofeedback was represented and investigated in 8 of the reviewed studies. The considered studies provide preliminary data of the usefulness of feedback-based techniques in the treatment of several dysfunctional eating behaviors (e.g., food craving, rumination). Due to the high heterogeneity of samples, outcome measures and feedback modalities, a meta-analysis in order to quantify the effectiveness of both biofeedback and neurofeedback was not performed. The results of this review suggest that feedback-based treatments may be useful in the treatment of several dysfunctional eating behaviors. The authors conclude that future well-designed studies with large clinical samples are needed in order to draw definitive conclusions.

## Clinical Trials & Studies

The Neurofeedback Collaborative Group (2021) performed a double-blind placebo-controlled randomized clinical trial of neurofeedback (NF) for attention-deficit/hyperactivity disorder (ADHD) with a 13-month follow-up. There were 142 participants, children aged 7-10 with a diagnosis of moderate/severe ADHD. The design was a 2-site, parallel-group, double-blind randomized comparison of active neurofeedback (NF) treatments to sham NF (control) treatments, for up to 38 treatments in a 14-week period, with follow-up at 6, 13, and 25 months. The primary outcome findings for both groups showed significant improvement ($p < 0.001$, $d = 1.5$) in analysis of the of parent/teacher-rated inattention from baseline to end of treatment and at the 13-month follow-up. However, NF was not significantly effective when compared to control treatment at either time point on this primary outcome ($d = 0.01$, $p = 0.965$ at treatment end; $d = 0.23$, $p = 0.412$ at 13-month follow-up). Responders (Clinical Global Impression-Improvement [CGI-I]) receiving active NF were 61% and 54% received control treatment ($p = 0.36$). A 10-month end of treatment follow-up suggested a minor improved inattention score for active NF; an increase from 27.4% end of treatment to 39.7% at 10 months. The 13-month follow-up showed no significant improvement from treatment end for NF ($d = 0.1$), with mild deterioration for control treatment ($d = -0.07$). Active NF required significantly less medication at the 13-month follow-up ($p = 0.012$). The authors acknowledge there was no significant effect of active NF beyond the control treatment, and particularly a lack of durability beyond 13 months; participants plan for reassessment at 25 months. Limitations such as long-term durability and lack of generalizability due to using only theta/beta NF protocols are indicators that continued and future research is necessary.

### Other Behavioral Disorders

Fielenbach et al. (2018) conducted an RCT to investigate the effects of a theta/sensorimotor rhythm (SMR) neurofeedback training protocol on levels of impulsivity, levels of drug craving, and actual drug intake in a population of forensic psychiatric patients with a diagnosis of substance use disorders (SUD). A total of 21 participants received 20 sessions of theta/SMR neurofeedback training in combination with treatment-as-usual (TAU). Findings of the intervention were compared with results from 21 participants who received TAU only. SMR magnitude showed a significant (P=.02) increase post training for patients in the neurofeedback training group, whereas theta magnitude did not change (P=.71). The described amount of drug craving as well as scores on the motor subscale of the Barratt Impulsivity Scale-11 decreased equally for patients in the neurofeedback training group and the TAU group. Other measures of impulsivity as well as drug intake did not change posttreatment. The results demonstrate that neurofeedback+TAU was not more effective than TAU only. The authors concluded that this study demonstrated evidence that forensic psychiatric patients are able to increase SMR magnitude over the course of neurofeedback training. However, at the group level, the increase in SMR activity was not related to any of the included impulsivity or drug craving measures. The authors stated that further research should address which patients would potentially benefit from neurofeedback training at an early stage of the employed training sessions.

## Guidelines & Consensus Statements

- *American Academy of Pediatrics (AAP)*
  - In the AAP's Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of ADHD in Children and Adolescents (2019), states that "Some nonmedication treatments for ADHD-related problems have either too little

evidence to recommend them or have been found to have little or no benefit. These include mindfulness, cognitive training, diet modification, EEG biofeedback, and supportive counseling."

- *Department of Veterans Affairs and Department of Defense (VA/DoD)*
  - The VA/DoD Clinical Practice Guidelines for the Management of Major Depressive Disorder (2022) indicates the following for complementary and alternative treatments:
    - For patients with major depressive disorder (MDD), there is insufficient evidence to recommend for or against the addition of biofeedback.

## U.S. Food and Drug Administration

**Neurofeedback/biofeedback devices** are considered a medical device when registered with the FDA. They are considered Class II devices and are exempt from 510(K) premarket notification requirements.
See the following for more information:
FDA website: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=882.5050.

## Centers for Medicare and Medicaid Services

Medicare does not have a National Coverage Determination (NCD) specifically for neurofeedback or biofeedback (with or without EEG guidance) used in treating individuals with behavioral or substance use disorders. Local Coverage Determinations (LCDs) exist for CPT codes 90875 and 90876. For behavioral health topics, refer to the LCDs for Outpatient Psychiatry and Psychology Services, Partial Hospitalization Programs and Psychiatry and Psychology Services.

Medicare has published NCD 30.1 Biofeedback Therapy and NCD 30.1.1 Biofeedback Therapy for the Treatment of Urinary Incontinence. Medicare states the biofeedback is covered only when it is reasonable and necessary for the individual patient for muscle re-education of specific muscle groups or for treating pathological muscle abnormalities of spasticity, incapacitating muscle spasm, or weakness, and more conventional treatments (heat, cold, massage, exercise, support) have not been successful. This therapy is not covered for treatment of ordinary muscle tension states or for psychosomatic conditions (www.cms.gov).

## Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member-specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other clinical criteria may apply.

| Procedure Codes | Description |
|---|---|
| 90875 | Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (e.g., insight oriented, behavior modifying or supportive psychotherapy); 30 minutes |
| 90876 | Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (e.g., insight oriented, behavior modifying or supportive psychotherapy); 45 minutes |
| 90901 | Biofeedback training by any modality |

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## Revision History

| Date | Summary of Changes |
|---|---|
| 06/15/2020 | Annual Review: updates to references/sourcing. |
| 06/21/2021 | Annual Review: updates to references/sourcing. |
| 06/21/2022 | Annual Review: updates to references/sourcing. |
| 07/18/2023 | Annual Review: updates to references/sourcing. |

## Appendix

Additional resources considered in support of this policy:

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