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PHARMACY BENEFIT COVERAGE GUIDELINE – 5.01.542

Medical Necessity Criteria for Medication Safety: Controlled Substances Utilization Service Program

Effective Date:	Jul. 1, 2026	RELATED GUIDELINES / POLICIES:
Last Revised:	Jun. 8, 2026	5.01.529 Management of Opioid Therapy
Replaces:	N/A	

Select a hyperlink below to be directed to that section.

COVERAGE GUIDELINES | CODING | RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

Clicking this icon returns you to the hyperlinks menu above.

Introduction

A controlled medication is a drug that is legal to use with a prescription but is highly regulated because of the potential for physical and mental dependence. Controlled medications are grouped into five classes by the Drug Enforcement Administration. The classes are based on a particular drug's medical use, safety, and potential for abuse and/or dependence. While the vast majority of people who get prescriptions for controlled medications use them responsibly, there are some cases where prescription patterns point to overuse, misuse, or giving or selling the medication to others. In such cases, this policy describes the steps to ensure how a person can get their needed medication in safe quantities through a single provider.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Coverage Guidelines

Restriction	Medical Necessity

One-provider restriction	**One-Provider restriction may be considered medically necessary when there is evidence of excessive use, misuse, non-medical use, or diversion of one or more controlled substances by a member, and when one or more attempts to contact and work with the member to establish a plan for appropriate management of controlled substances via case management, chemical dependency treatment, enrollment in a pain management program, or self-imposed restriction to one prescriber, have failed.**
	
	When restricted to one-provider, a single provider will be identified for coverage of prescriptions of all controlled substances for the member. The pharmacy claims system will be locked to prevent coverage of prescriptions of controlled medications unless they are prescribed by that provider.
	
	The existence of any one or more of the following criteria or behaviors may be used to identify individuals who may be engaged in the excessive use, misuse, non-medical use, or diversion of controlled substances:
	• Pattern of simultaneous or overlapping controlled substance prescribing involving multiple prescribers and/or pharmacies. This includes but is not limited to:
	  ○ Multiple prescribers of same or similar controlled substances within overlapping timeframes
	  ○ Fills of controlled substances at multiple pharmacies within overlapping timeframes
	• Long-term, unusually high and escalating doses of controlled substances. This includes but is not limited to:
	  ○ Total daily opioid dose of more than 120mg Morphine Equivalent Dose (MED), also known as Morphine Milligram Equivalent (MME)
	• Frequent early refill requests
	• Altered (any occurrence) or forged prescriptions
	• Multiple reports of misplaced, lost, or stolen medications or prescriptions
	• Increasing symptoms in spite of being on controlled substances

Restriction	Medical Necessity

	• Declining activity or functioning in spite of being prescribed controlled substances
	• Missing medical appointments except when a refill is expected or needed
	• Unwilling to try other non-controlled pharmacologic and non-pharmacologic treatments
	• Insistence on a specific controlled substance
	• Reports of, or appearing to be:
	  ○ Intoxicated, somnolent, or sedated; or
	  ○ Exhibiting withdrawal symptoms
	• Abnormal results on drug screening tests, such as opioids or cannabinoids when none should be present, or absence of opioid when they are being prescribed and should be present on testing
	• Unwillingness or inability to take medications as prescribed
	• Concurrent prescriptions for buprenorphine (Suboxone or Subutex) and an opioid
	• Unwillingness or failure to engage in evidence-based individual management methods that may include but are not limited to the following:
	  ○ Pain management by a single provider, with all pain medications prescribed by that provider
	  ○ Pain management agreement between the member and the provider outlining both the provider and member's obligations surrounding the prescription, fulfillment, and management of controlled substances as well as a clear path of action when said contract is broken
	  ○ Periodic drug screening tests
	  ○ Attempts to taper controlled substance dosing as medically appropriate, using appropriate non-controlled drugs and nonpharmacologic treatments to optimize symptom management while minimizing controlled substance use

Coding

N/A

Related Information

Benefit Application

This policy is managed through the pharmacy benefit.

Evidence Review

Controlled substances are defined and categorized by the Drug Enforcement Administration (DEA) under classification C1 through C5 (or Schedule I to Schedule V). The categorization is based upon a substance's medical use, potential for abuse, and safety or dependence liability. The medical policy encompasses all controlled substances; given all have potential for abuse; the data and evidence below are mainly focused on narcotics or opioids for the treatment of chronic noncancer pain (CNCP).

There are numerous available treatment modalities for CNCP including pharmacologic and non-pharmacologic interventions. Among these, opioids, known for their strong analgesic properties, have gained popularity over the past two decades. Their use is established in the setting of acute, postoperative pain, cancer pain and pain at the end of life. In contrast, the role of opioids for managing CNCP is controversial, owing to the paucity of high-quality evidence demonstrating effectiveness and safety in this individual population. Existing data are limited by suboptimal study designs characterized by largely observational, non-comparative studies, short-term follow-up and significant withdrawal rates. Two Danish epidemiologic studies showed that in a region where opioids are prescribed liberally for pain, the individuals receiving opioid analgesics reported worse pain, higher utilization of healthcare, and lower activity levels compared to matched controls. A population-based cohort study from the same authors showed the odds of recovery from chronic pain were four times higher in individuals not using opioids, compared with those using opioids for pain management. While opioid analgesics are indeed effective in some individuals, they may not be suitable for all. Therefore, it is to the benefit of individuals to constructively address the issue of over-prescribing, over-use, and misuse of opioid medications. Due to the substantial evidence of increasing morbidity and

mortality associated with prescription opioid use, this medical policy which will guide appropriate use of controlled substances is necessary.

Opioids produce both analgesia and euphoria. The mood-altering action of opioids in addition to the physical dependence and addictive qualities of this class of drugs encourages abuse (nonmedical use). Opioid abuse and misuse occurs for a variety of reasons, including self-medication, use for reward, compulsive use because of addiction, and diversion for profit. Individuals with chronic pain and co-occurring substance use disorders and/or mental health disorders, are at higher risk for misuse of prescribed opioids. The increasing use of opioid analgesics for treating chronic noncancer pain, and the introduction of high-dose, extended release oral tablet formulations of opioids with good bioavailability, has increased opportunities for the illicit use of prescription opioids. Such use has become a major societal problem, reaching epidemic proportions; it now exceeds the use of street narcotics in the United States. In April 2011, the White House unveiled a multi-agency plan aimed at reducing the "epidemic" of prescription drug abuse in the United States. The plan is a collaborative effort involving various agencies. According to the director of the White House Office of National Drug Control Policy (ONDCP) this plan "provides a national framework for reducing prescription drug abuse and the diversion of prescription drugs for recreational use." Advocacy for prescribing opioids despite the lack of long-term effectiveness, unproven standards, and guidelines with conflicting recommendations, contributes to the epidemic of opioid abuse. Clinical decisions and practice recommendations must rely to a significant extent on practice experience and consensus rather than research evidence in assessing the treatment of acute and chronic noncancer pain.

Evidence supporting long-term benefit of opioid analgesics for managing CNCP is lacking, owing to the predominantly observational and short-term nature of studies. Furthermore, data comparing various opioids and opioids to other analgesics or to nonpharmacologic modalities are also lacking. The harms from prescription opioids to individuals and others are substantial and increasingly recognized. When opioids are used, initial risk assessment, careful dose titration and monitoring including functional outcomes, while educating individuals is key. It is also important to recognize individuals at highest risk of adverse events – those receiving high opioid doses and from multiple providers.

Various guidelines which have been published all agree that prevention of controlled substance abuse is key. For providers, the ability to identify individuals who are most "at-risk" for developing prescription drug abuse prior to initiation of opioids is critical. Screening individuals to determine their risk of drug abuse prior to beginning opioid therapy is considered standard of practice. Several risk factors have been described and include sociodemographic factors, pain and drug-related factors, genetics and environment, psychosocial and family history, psychopathology, and alcohol and substance use disorders. It is suggested that the risk of

prescription drug abuse is greatest when risk factors in 3 categories occur in the same individual. In the absence of psychosocial comorbidities and genetic predisposition, pain individuals on stable doses of opioids in a controlled setting are unlikely to abuse opioids or develop addiction. On the other hand, individuals with a personal or family history of substance abuse, and psychosocial comorbidity, are at increased risk, especially if treatment with opioids is not carefully structured and monitored (Ballantyne). Individuals who are undergoing chronic opioid therapy for pain have been shown to have significantly higher Screener and Opioid Assessment for Patients with Pain (SOAPP), Current Opioid Misuse Measure (COMM), and drug misuse index (DMI) scores ($p<0.001$), indicating a higher risk for misuse. In a population-based observational study, subjects with evidence of doctor-shopping were significantly more likely to have a previous history of overdose, or a history of substance abuse. These data suggest that both individuals and providers may benefit from other treatment options before beginning opioid therapy for pain such as exercise and cognitive behavioral therapy for chronic management.

Indicators of Potential Excessive Use, Misuse, Non-Medical Use, or Diversion of Controlled Substance

When treatment with controlled medications has already been initiated, identification of indicators of potential excessive use, misuse, non-medical use, or diversion becomes critical to preventing or intervening in cases of abuse, addiction, or serious adverse events. Clinical experience and studies have identified a number of factors that indicate potential excessive use, misuse, non-medical use, or diversion. There is no factor that is absolutely indicative of excessive use, misuse, non-medical use; identification of one or more factors requires individual patient evaluation to differentiate between inappropriate use and possible appropriate use given a individual's unique clinical circumstances.

The most common indicators of potential excessive use, misuse, non-medical use, or diversion are doctor shopping, and high or escalating doses of opioids. These two are widely used criterion to identify people who may be engaged in non-medical use of controlled substances.

Cantrell et al. use the following criteria for identification of 'doctor shopping': 2 or more prescribers within 30 days, greater than 4 during 1 year, and greater than 5 during 1 year. Pradel et al. defined doctor shopping as the amount of drug obtained through doctor shopping compared with the amount intended to be prescribed. The use of "pill mills," in which a prescriber provides ready access to prescriptions or pills, can also be considered a form of doctor shopping.

Doctor shopping is directly associated with the incidence of deaths from opioids. Hall et al. reviewed characteristics of decedents who died of prescription drugs in West Virginia and reported that opioid analgesics accounted for 93% of deaths. The authors determined the prescription history of the drug associated with each fatality. Individuals who had received controlled drugs from 5 or more prescribers in the year before death were defined as engaging in "doctor shopping," whereas those whose death was not associated with a valid prescription were considered to have obtained their drugs through "diversion." Doctor shopping was associated with 63 (21%) of the fatalities and diversion was associated with 186 (63%) of the fatalities. Of the 295 total decedents, 279 (95%) had at least 1 indicator of substance abuse, and those differed according to whether the drug was obtained through diversion or doctor shopping. A report from the CDC reported a rise in prescription opioid-related deaths of 68% between 1999 and 2004. The CDC also studied prescription drug overdoses and found that 10% of individuals seeing multiple doctors and typically involved in drug diversion accounted for 40% of the overdoses (see figure below). This illustrates that individuals are more likely to overdose if they are seeing multiple doctors or if they are on a high dose of controlled drug.

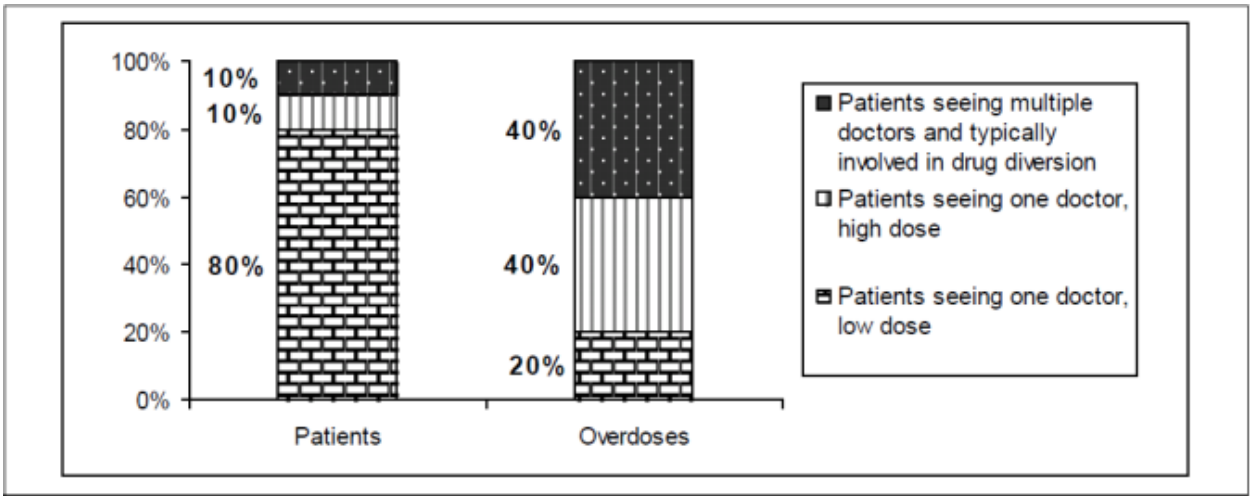

Fig. 17. *Percentage of patients and prescription drug overdoses, by risk group – United States.*
Source: Centers for Disease Control and Prevention. CDC grand rounds: Prescription drug overdoses – a U.S. epidemic. MMWR. Morb. Mortal Wkly. Rep. 61, 10-13 (2012) (34).

High or escalating doses of opioids are also associated with a greater incidence of adverse outcomes, including opioid-related fatal overdoses. In a study of 9,940 adults receiving long-term opioid therapy for chronic noncancer pain, those who received 100mg/day or more of morphine equivalent had an 8.9-fold increase in overdose risk (95% CI 4.0-19.7). Although there is not uniform agreement on what constitutes an excessive dose of opioid, there is a general

consensus that doses above 200 mg Morphine Equivalent Dose (MED) total daily dose should be considered to be excessive.

In addition to doctor shopping and high or escalating doses, other factors that have been identified as indicators of potential excessive use, misuse, non-medical use, or diversion include multiple prescribers of controlled substances, use of multiple pharmacies to fill controlled substances prescriptions, the number of controlled prescriptions in defined time periods, and overlapping or concomitant controlled substances prescriptions. Manchikanti et al. noted that available national data overwhelmingly suggest that the increased supply of opioids, high medical users, doctor shoppers, and individuals with multiple comorbid factors contribute to the majority of fatalities. They observed that on average, individuals were exposed to 2 different opioids and had 3 different opioid prescribers. Braker et al. found that a retrospective review of payer opioid prescription data and individual charts from a rural family medicine group identified individuals with 3 or more prescriptions (average 8.4; standard deviation = 5.5; range 3-28) from 2 or more providers (average 3.7; SD = 1.8, range 2-10) over a 6-month period. Concurrent use of nonopioid analgesics, escalating opioid dosage, and number of providers were the best predictors for adverse events. Findings from other studies are summarized in table 1 below.

Table 1: Criteria Showing Potential Abuse

Author	Criteria Which Identified Potential Abuse
Gonzalez et al.	Members who received opioid prescriptions from 3 or more prescribers at 3 or more pharmacies in a 3-month identification period
Sehgal et al.	Patients with 3 or more prescriptions from 2 or more providers over a 6-month period; concurrent use of nonopioid analgesics; escalating opioid dosage; and number of providers
Cepeda et al.	Overlapping or concomitant prescriptions defined as at least 1 day of overlapping dispensing of prescriptions written by two or more different prescribers at any time during an 18-month period; Authors concluded that having two or more overlapping prescriptions written by different prescribers and filled at 3 or more pharmacies differentiates opioids from diuretics and likely constitutes shopping behavior.
Dunn et al.	3 or more prescriptions for opioid analgesics in the first 90 days of the episode

Parente et al. developed a claims-based method to identify individuals who may be misusing controlled substances and prescribers who may be providing pharmacologic management that warrants evaluation. They drew data from health insurance claims and used an 11-member

multidisciplinary expert panel to define criteria for identifying controlled substance patterns of utilization requiring evaluation. The goal in defining the criteria was to have this be widely applicable to claims databases to identify possible abuse or diversion of controlled substances by individuals or mismanagement by prescribers. The table below outlines the ten patterns that were most positively associated with identification of a misuse case.

Table 1. Prevalence Results for Top 10 Controlled Substance Patterns of Utilization Requiring Evaluation (CS-PURE) Most Positively Associated With the Probability of Identifying a Misuse Case

CS-PURE	Pattern of Controlled Substance Misuse	Period Prevalence for 2000, %		Projected No. of Patients in a 500 000-Member Health Plan
		Database 1 (n = 2 927 237)	Database 2 (n = 782 880)	
01	Multiple prescribers (≥6 prescribers for same drug)	0.213	0.252	1116
02	Multiple pharmacies (≥4 different pharmacies for same drug)	0.132	0.135	664
03	Chronic use of carisoprodol (≥4 prescriptions in 6 mo)	0.125	0.105	597
04	Continuous overlap of ≥2 different benzodiazepines for ≥30 d, when 1 is for alprazolam	0.059	0.070	310
05	Estimated ≥4 g/d of acetaminophen	0.028	0.012	118
06	≥2 Prescriptions for meperidine hydrochloride with >2-day supply	0.016	0.023	88
07	Chronic use of butorphanol[AUTHOR: OR "BUTORPHANOL TARTRATE"?] (≥4 prescriptions in 6 mo)	0.015	0.019	81
08	Continuous overlap of ≥2 different benzodiazepines for ≥90 d, when 1 is for clonazepam	0.005	0.007	28
09	Continuous overlap of ≥2 different benzodiazepines for ≥90 d, when 1 is for diazepam	0.003	0.004	17
10	Overlap of ≥2 different sustained-release or long-acting opioids for ≥90 consecutive days	0.001	0.001	5

Additional factors that have been identified as potential indicators of excessive use, misuse, non-medical use, or diversion include frequent early refill requests; altered or forged prescriptions; multiple reports of misplaced, lost, or stolen medications or prescriptions; insistence on a specific controlled substance; missing medical appointments except when a controlled substance refill is expected or needed; increasing symptoms in spite of being on controlled substances; declining activity or functioning in spite of being on controlled substances; refusal to try other non-controlled pharmacologic and non-pharmacologic treatments; reports of or appearing to be intoxicated, somnolent, sedated, or exhibiting withdrawal symptoms; positive results for controlled medications on drug screening tests when none have been prescribed; absence of positive results for controlled medications on drug screening tests when they are being prescribed; concurrent prescriptions for buprenorphine (Suboxone or Subutex) and an opioid; unwillingness to take medications as prescribed; and unwillingness or failure to engage in evidence-based individual management methods.

Although most published studies focus on steps that providers can take to identify individuals who are displaying evidence of possible excessive use, misuse, non-medical use, or diversion, a small but growing literature is establishing evidence of actions that can be taken by health insurance companies and managed care companies. For example, Gonzalez et al studied the impact of a care coordination intervention by a managed care organization after identification of potential opioid misuse. Using their database of prescription claims, the organization identified members who filled controlled opioid medications prescribed by three or more providers and filled at three or more pharmacies in a three-month period. Half of these members were randomized to an intervention arm in which a letter was sent quarterly to the prescriber explaining their individual was receiving multiple opioid prescriptions filled at multiple locations. They were also sent a clinical medication report detailing each opioid prescription that was filled by their individual in the past three months, at which pharmacies, and who the other prescribers were. The prescriber was encouraged to contact the other prescribers listed in an effort to coordinate care. For members in the control group, generic letters were sent to the prescriber discussing the importance of opioid management, but no details or identifying information were given. The members in the intervention group showed a 24% greater reduction in number of prescribers, 16% greater reduction in the number of pharmacies used, and a 15% greater reduction in number of controlled opioid prescriptions compared to the control group. The authors concluded that managed care organizations have the opportunity to identify potential opioid misuse and implement care coordination interventions. Additionally, the study revealed individuals receiving opioid prescriptions from multiple prescribers and pharmacies during short time intervals is evidence of uncoordinated pain management and suggests misuse of opioid medications. Although dependence or addiction to opioid medications cannot be diagnosed by analysis of prescription claims alone, prescription claims may be used as a tool to guide future prescribing and to pinpoint factors associated with the uncoordinated care of a member.

One Prescriber Restrictions

Limiting the prescription and management of controlled substances to a single prescriber has become standard of care for individuals receiving chronic treatment for non-cancer disorders. As noted in the previous section, evidence-based studies have documented a direct relationship between the number of prescribers of opioids for an individual and the severity of adverse effects including opioid-related deaths. Conversely, limiting opioid prescription and management to a single prescriber significantly reduces the occurrence of severe adverse effects and fatal outcomes associated with treatment with opioids.

Systematic reviews of evidence-based treatment guidelines for pain management demonstrate almost universal agreement that controlled medications should be prescribed and managed by a single prescribing physician, or a single treatment team for individuals who are managed by a clinic team. When a individual's health care is being managed by multiple provides, which is common, all providers should agree on a single designated prescriber for controlled pain medications.

Systematic reviews of evidence-based treatment guidelines have also established the usefulness of individual-provider agreements, also known as individual contracts, when controlled pain medications are utilized for the management of chronic non-cancer pain. Reviews of the specific components of individual-provider agreements have consistently identified the identification and utilization of a single prescriber of controlled medications as a key component of such agreements.

Government agencies have also become increasingly concerned about escalating use of controlled prescription medications, particularly opioids due to the alarming increase in the number of deaths from accidental overdoses. Various state and Federal agencies have devised programs targeting excessive use of opioids, including prescription monitoring programs that allow prescribing clinicians to access databases listing all controlled medications prescribed to individuals. The state of Washington has also issued mandatory rules for the management of chronic non-cancer pain. Based on the best available evidence, the rules stipulate, among other provisions, that chronic non-cancer pain individuals receive all chronic pain management prescriptions from one physician.

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History

Date	Comments
10/09/12	New policy added to Prescription Drug section. Policy approved with 90-day provide notification hold. The policy is effective February 11, 2013.

Date	Comments
01/22/13	Policy effective date delayed and is now April 1, 2013.
03/11/13	Replace policy. Policy updated within the Policy Guidelines, clarifying criteria added, removed and rearranged; Description section removed, references added, removed, renumbered and updated. Policy effective date remains April 1, 2013.
07/08/13	Minor Update – Clarification was added to the policy that it is managed through the member's pharmacy benefit; this is now listed in the header and within the coding section.
12/08/14	Annual Review. Converted to Benefit Coverage Guideline template. No change in policy statement.
09/08/15	Annual Review. No change in coverage statements.
11/01/16	Annual Review, approved October 11, 2016. Updated Coverage Guideline sentence.
09/01/17	Annual Review, approved August 22, 2017. No changes to coverage guidelines.
11/01/18	Annual Review, approved October 26, 2018. No changes to coverage guidelines.
01/01/20	Annual Review, approved December 10, 2019. No changes to coverage guidelines.
12/01/20	Annual Review, approved November 19, 2020. No changes to coverage guidelines.
10/01/21	Annual Review, approved September 23, 2021. No changes to coverage guidelines.
11/01/22	Annual Review, approved October 10, 2022. No changes to coverage guidelines. Changed the wording from "patient" to "individual" throughout the policy for standardization.
06/01/23	Annual Review, approved May 22, 2023. No changes to coverage guidelines.
06/01/24	Annual Review, approved May 24, 2024. No changes to coverage guidelines.
04/01/25	Annual Review, approved March 24, 2025. No changes to coverage guidelines.
07/01/26	Annual Review, approved June 8, 2026. No changes to coverage guidelines.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2026 Premera All Rights Reserved.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.