Cigna Drug and Biologic Coverage Policy

Subject **Controlled Substance Analgesic and Narcotic Antagonist Quantity Limitations**

Effective Date……7/1/2018
Next Review Date……..5/15/2019
Coverage Policy Number……..1706

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Related Coverage Resources

Transmucosal Fentanyl

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INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Coverage Policy

Cigna covers drugs in excess of the Quantity Limit requirements, in accordance with benefit plan specifications, as medically necessary when the following criteria have been met:

- Dosage, frequency, site of administration, and duration of therapy is not contraindicated or otherwise not recommended in the FDA product information (Label).
- Dosage, frequency, site of administration, and duration of therapy should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy as applicable
- For opioid therapy only, attestation that opioids will be prescribed in accordance with current clinical practice guidelines AND that an assessment of risks, harms, and goals consistent with an opioid agreement (or similar agreement) has been undertaken.

Specific Quantity Limitations:

LONG-ACTING OPIOIDS DRUG	Quantity Limitation
FENTANYL	
Fentanyl (Duragesic) Patch	15 patches per 30 days
HYDROCODONE	

LONG-ACTING OPIOIDS DRUG	Quantity Limitation
Hydrocodone (Hysingla ER)Tablet	1 tablet per day
Hydrocodone (Zohydro ER)Capsule	• 10 mg, 15 mg, 20 mg, 30 mg, 40 mg: 2 capsules per day • 50 mg: 4 capsules per day
HYDROMORPHONE	
Hydromorphone (Exalgo) Tablet	• 8mg: 1 tablet per day • 12mg, 32mg: 2 tablets per day • 16 mg: 4 tablets per day
MORPHINE SULFATE	
Morphine sulfate (Avinza) Capsule	3 capsules per day
Morphine sulfate (Kadian) Capsule	3 capsules per day
Morphine sulfate (MS Contin) Tablet	4 tablets per day
MORPHINE-NALTREXONE	
Morphine-Naltrexone (Embeda) Capsule	3 capsules per day
OXYCODONE	
Oxycodone (Oxycontin)Tablet	• 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg: 2 tablets per day • 80 mg: 4 tablets per day
Oxycodone (Xtampza ER) Capsule	• 9mg, 13.5mg,18mg: 2 capsules per day • 27mg: 4 capsules per day • 36mg: 8 capsules per day
OXYMORPHONE	
Oxymorphone (Opana ER) Tablet	• 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, 30 mg: 2 tablets per day • 40 mg: 4 tablets per day

DETOXIFICATION AGENTS DRUG	Quantity Limitation
Naloxone (Evzio) injection	0.8 mL (2 auto-injectors) per 30 days
Naloxone (Narcan) nasal spray	2 units per 30 days
Naltrexone tablet	180 tablets per 30 days

HEADACHE COMBINATIONS DRUG	Quantity Limitation
Butalbital-caffeine-aspirin (Fiorinal) capsule	Maximum daily dose – 6 capsules/tablets

PAIN CONTROL DRUG	Quantity Limitation
Buprenorphine (Butrans) patch	4 patches per 28 days
Buprenorphine (Belbuca) buccal film	2 films per day
Butorphanol nasal spray	6 nasal units per 30 days
Tapentadol (Nucynta) tablet Tapentadol (Nucynta ER) extended-release tablet	6 tablets per day 2 tablets per day
Tramadol (Ultram) tablet Tramadol ER (Conzip) capsule Tramadol ER (Ultram ER) tablet Tramadol HCL ER 150mg capsule	8 tablets per day 1 capsule per day 1 tablet per day 1 capsule per day
Tramadol/Acetaminophen (Ultracet) tablet	8 tablets per day

PARENTERAL SHORT-ACTING OPIOIDS
Note: Injectable opioid medications are specifically excluded under most benefit plans. Please refer to the applicable benefit plan document to determine benefit availability and the terms and conditions of coverage. When coverage is available for injectable opioid therapy, the quantity limitation is 1 mL per 30 days.

General Background

The Institute of Medicine (IOM) estimates that at least 1.5 million preventable adverse drug events occur within the healthcare system each year. The costs of these preventable adverse drug events have been estimated to exceed $4 billion annually.

Certain preventable adverse drug events relate to improper medication use. The Food and Drug Administration (FDA) launched the Safe Use Initiative to avoid improper medication use. Improper medication use increases the risk of harm from medication, often resulting in hundreds of thousands of injuries or deaths each year. Many of these injuries and adverse events could have been prevented with currently available knowledge.
Quantity Limitations are placed on pharmaceutical products to assure appropriate dosing and safe medication use as published in the FDA Product Information or "Label".

Employers that have selected Cigna Health Care benefit plans may choose Quantity Limitations as a part of the pharmacy benefit program.

The rationale for each drug or therapy group of Quantity Limitations is defined in the table below.

Therapeutic Category	Drug	Rationale
Long Acting Opioids		
	Fentanyl (Duragesic) patch	The FDA does not provide a recommended dose limit. A limit is in place for safety reasons (to provide a review of doses exceeding the usual dosing schedule).
	Hydrocodone (Zohydro ER)	The FDA does not provide a recommended dose limit. A limit is in place for safety reasons (to provide a review of doses exceeding what was studied in clinical trials).

Therapeutic Category	Drug	Rationale
	Hydromorphone (Exalgo)	The FDA does not provide a recommended dose limit. A limit is in place for safety reasons (to provide a review of doses exceeding what was studied in clinical trials).
	Morphine sulfate (Avinza, Kadian, MS Contin)	The FDA does not provide a recommended dose limit. A limit is in place for safety reasons (to provide a review of doses exceeding either the usual dosing schedule or a more frequent than recommended schedule [to allow for patient variability in dosing requirements]).
	Morphine sulfate/naltrexone (Embeda) extended-release tablet	The FDA does not provide a recommended dose limit. A limit is in place for safety reasons (to provide a review of doses exceeding either the usual dosing schedule or a more frequent than recommended schedule [to allow for patient variability in dosing requirements]).
	Oxycodone (OxyContin)	The FDA does not provide a recommended dose limit. A limit is in place for safety reasons (to provide a review of doses exceeding the usual dosing schedule).
	Oxycodone (Xtampza ER)	Limits to FDA recommended daily dose of therapy based upon efficacy and safety studies. (The FDA maximum recommended daily dose is 288 mg per day (eight 36 mg capsules, equivalent to 320 mg oxycodone HCl per day)
Detoxification Agents		
	Naloxone (Evzio) injection	The FDA does not provide a recommended dose limit. A limit is in place for safety reasons (to provide a review of doses exceeding the usual dosing schedule).
	Naloxone (Narcan) nasal spray	The FDA does not provide a recommended dose limit. A limit is in place for safety reasons (to provide a review of doses exceeding the usual dosing schedule).
	Naltrexone tablet	The FDA does not provide a recommended dose limit. A limit is in place for safety reasons (to provide a review of doses exceeding the usual dosing schedule).
Headache Combinations		
	Butalbital/aspirin/caffeine (Fiorinal) capsule	Limits to FDA recommended daily dose of therapy based upon efficacy and safety studies (The FDA maximum recommended daily dose is 6 capsules).
Pain Control		
	Buprenorphine (Butrans) patch	Limits to FDA recommended daily dose of therapy based upon efficacy and safety studies (The FDA maximum recommended dose is (1) 20mcg/hour patch every 7 days).
	Buprenorphine (Belbuca) buccal film	Limits to FDA recommended daily dose of therapy based upon efficacy and safety studies (The FDA maximum recommended dose is 900 micrograms every 12 hours).
	Butorphanol nasal spray	The FDA does not provide a recommended dose limit. A limit is in place for safety reasons (to provide a

Therapeutic Category	Drug	Rationale
		review of doses exceeding the usual dosing schedule).
	Tapentadol (Nucynta) tablet	Limits to FDA recommended daily dose of therapy based upon efficacy and safety studies (The FDA maximum recommended daily dose is 600 milligrams).
	Tapentadol (Nucynta ER) extended-release tablet	Limits to FDA recommended daily dose of therapy based upon efficacy and safety studies (The FDA maximum recommended daily dose is 500 milligrams).
	Tramadol (Ultram) tablet	Limits to FDA recommended daily dose of therapy based upon efficacy and safety studies (The FDA maximum recommended daily dose is 400 milligrams).
	Tramadol (Conzip) extended-release capsule	Limits to FDA recommended daily dose of therapy based upon efficacy and safety studies (The FDA maximum recommended daily dose is 300 milligrams).
	Tramadol (Ultram ER) extended-release tablet	Limits to FDA recommended daily dose of therapy based upon efficacy and safety studies (The FDA maximum recommended daily dose is 300 milligrams).
	Tramadol/ acetaminophen (Ultracet) tablet	Limits to FDA recommended daily dose of therapy based upon efficacy and safety studies (The FDA maximum recommended daily dose is 8 tablets).

Coding/Billing Information

Note: Quantity Limitations is typically covered under pharmacy benefit plans. Certain prescription drugs require an authorization for coverage to ensure that appropriate treatment regimens are followed. Medical drug coding and diagnosis codes, however, are generally not required for pharmacy claims submissions, therefore, this section is not in use.

References

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4. U.S. Department of Health and Human Services Food and Drug Administration (FDA). FDA Safe Use Initiative. Nov 4, 2009. Accessed 4/18/2017. Available at http://www.fda.gov/downloads/Drugs/DrugSafety/UCM188961.pdf
5. U.S. Food and Drug Administration. Drugs@FDA. U.S. Department of Health & Human Services: http://www.accessdata.fda.gov/scripts/cder/drugsatfda/.