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Drug Use Evaluation: Pregabalin – Indication Review

Plain Language Summary:

- Should the Oregon Health Plan change the current Medicaid policy for pregabalin to cover conditions that are not approved by the Food and Drug Administration (FDA)?
- Pregabalin can be prescribed for nerve pain. It also helps decrease anxiety for people with generalized anxiety disorder when it is prescribed with an antidepressant. Antidepressants that improve symptoms for people with generalized anxiety include selective serotonin reuptake inhibitors (SSRIs) and serotonin norepinephrine reuptake inhibitors (SNRIs).
- Studies have not shown that pregabalin improves pain in people with other pain-related conditions that are not FDA-approved.
- A review of Medicaid claims shows that providers commonly prescribe pregabalin for conditions that are not approved by the FDA. About 14% of people with claims for pregabalin have a diagnosis of generalized anxiety disorder.
- Currently, providers must tell Medicaid why they are prescribing pregabalin before Medicaid Open Card will pay for the prescription. This process is called prior authorization. This analysis of Medicaid data shows that prior authorization may decrease use of pregabalin for conditions where there is no benefit. But it may also delay care for people with generalized anxiety disorder or other conditions where there is benefit.
- The Mental Health Clinical Advisory Group recommended that pregabalin be available for people with generalized anxiety disorder when prescribed with an SSRI or SNRI. They recommended removal of prior authorization to reduce barriers to treatment for this population.
- We recommend that immediate-release pregabalin be available as a preferred option for people with Medicaid Open Card. The Pharmacy and Therapeutics Committee should consider removal of prior authorization for pregabalin or automatic approval of requests for preferred pregabalin when it is prescribed for generalized anxiety disorder.

Research Questions:

- What medical diagnoses are present in Oregon FFS Medicaid members prescribed pregabalin that are potential indications for therapy?
- What types of providers prescribe pregabalin in Oregon FFS Medicaid members?
- In people with a prescription for pregabalin, how many members were recently prescribed an SSRI or SNRI?

Conclusions:

- Overall, less than half of OHP members with FFS claims for pregabalin had an FDA-approved diagnosis (48%). The most common diagnoses identified in medical claims for members with claims for pregabalin included diabetic neuropathy or diabetes (29%), other neuropathies and nerve injury (14%), and fibromyalgia (17%).
- A diagnosis of generalized anxiety disorder (GAD) was present in the medical claims for 14% of members (n=26). Comorbid diagnoses were common in people with GAD, and 14 people (54%) with a diagnosis of GAD also had another FDA-approved diagnosis for pregabalin in their medical claims.

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- General practitioners accounted for the majority of pregabalin claims and most commonly included family medicine physicians, family nurse practitioners, internal medicine physicians, and physician assistants.
- Less than half of members with a diagnosis of GAD were prescribed first-line therapy with an SSRI or SNRI (46%) in the previous month. Previous therapy with an SSRI or SNRI was even less common in patients without a GAD diagnosis.

Recommendations:

- No changes were recommended to prior authorization criteria or preferred drug status at this time.
- Evaluate evidence for efficacy and safety of pregabalin and gabapentin for off-label conditions.

Background

Use of gabapentinoids, including pregabalin, has been rising. Between 2012 and 2016, spending on pregabalin grew from $2 billion to nearly $4.5 billion. In a 2022 study, approximately 1 in 5 U.S. adults with chronic pain were receiving a gabapentinoid.[1,2] Much of the increased use has been attributed to the search for alternatives to opioids for the management of chronic pain. New guidance from the Centers for Disease Control calls for even greater use of non-opioid analgesics, including pregabalin.[3] The guidelines suggest considering gabapentin or pregabalin for certain chronic pain conditions, including diabetic peripheral neuropathy, postherpetic neuralgia, and fibromyalgia.[3] The guidelines also indicate that they are associated with only small to moderate improvements and are not without adverse events such as blurred vision, cognitive effects, sedation, weight gain, dizziness, peripheral edema, and risks of respiratory depression and overdose when used in combination with opioids.[3]

Evidence directly comparing gabapentin to pregabalin are limited and are generally of poor quality with small sample sizes.[4] Among these small trials for chronic neuropathic pain, results are inconsistent with some trials showing small differences between gabapentin and pregabalin and the majority showing them to be equal.[4] Overall, there is insufficient evidence to discern the superiority of one agent over another.

For FDA approved indications, overall effect size of pregabalin in clinical studies is small.[4] Five studies were submitted to FDA for approval for diabetic peripheral neuropathy. Of those, the FDA rated three as being supportive, one as partly supportive and one as negative. Overall, the reduction in pain is modest, as measured on a 11-point Likert scale (ranging from 0-10). Additionally, the placebo response was at least 50% as large as the response to any pregabalin dose. For the treatment of fibromyalgia, there was a small difference seen in mean pain score with pregabalin 300 mg/day, 450 mg/day and 600 mg/day compared to placebo (difference of -0.71 to -1.0) with little additional benefit with the highest dose but more discontinuations due to adverse events.[4] Finally, cognitive adverse effects was a significant concern of FDA and most trials excluded patients from using other centrally acting medications during the study period, including opioids, which may underestimate adverse effects.

In contrast to the single pain indication for gabapentin, pregabalin is FDA approved for four pain related conditions, but it has been reported that most of the use is for off-label indications unsupported by evidence. There have been negative studies showing no significant benefit with pregabalin over placebo for various chronic pain conditions, including sciatica pain, human immunodeficiency virus (HIV) neuropathy, chronic sickle cell pain, acute zoster pain, and back pain.[5-7]

FDA-approved indications for immediate-release pregabalin include neuropathic pain associated with diabetic peripheral neuropathy, postherpatic neuralgia, neuropathic pain associated with spinal cord injury, fibromyalgia, and treatment of partial-onset seizures. Extended release formulations are only FDA approved to treat neuropathic pain associated with diabetic peripheral neuropathy and postherpatic neuralgia. A variety of off-label conditions have been cited in the literature including:[9,10]

- acute and chronic pain conditions such as post-operative, dental, cancer, or sickle-cell pain

- neuropathic conditions such as trigeminal neuralgia, familial dysautonomia, essential tremor, and other polyneuropathies
- genitourinary conditions such as uremic pruritus, and ureteral stent-related symptoms
- psychiatric conditions such as GAD and social anxiety disorder
- sleep-related conditions such as restless leg syndrome
- vasomotor symptoms associated with menopause
- alcohol use disorder and alcohol withdrawal symptoms

In the OHP FFS program, PA is required for pregabalin. The goal of the PA is to limit use to FDA-approved and OHP-funded indications. Common conditions that are unfunded on the prioritized list include restless leg syndrome, fibromyalgia, and some polyneuropathies. Gabapentin tablets and capsules are currently preferred products and are available without PA. Both drugs are categorized under Oregon law as physical health drugs, so they are not carved out from coordinated care organization (CCO) coverage.

In February 2022, the Mental Health Clinical Advisory Group (MHCAG) developed treatment algorithms for generalized anxiety disorder (GAD). Pregabalin is recommended as first-line adjunct treatment for patient with GAD in conjunction with a SSRI/SNRI. The MHCAG discussed the role of pregabalin in the OHP FFS program and made the following recommendations to the Pharmacy and Therapeutics (P & T) Committee for consideration:[11]

- Recommendation 1: Remove OHP FFS PA for pregabalin immediate-release (IR) capsule products.
    - Reason: The MHCAG recommends pregabalin IR as a first-line adjunct for patients with generalized anxiety disorder (GAD) on a SSRI/SNRI. Pregabalin IR has proven to be relatively safe, tolerable and effective for many conditions. The IR capsules have been generic for several years and is inexpensive.
- Recommendation 2: Should the P & T Committee not agree with the MHCAG's first recommendation, the MHCAG asks that the P & T Committee consider this alternative: Add GAD to Table 1 of OHP FFS PA for pregabalin IR and do not require prior treatment or intolerance to gabapentin.
    - Reason: Gabapentin does not have evidence for treatment of GAD.

Methods:
OHP members were identified for inclusion based on paid or denied FFS claims for pregabalin (HSN 026470). The evaluation window for pregabalin claims was from 7/1/21 to 6/30/22. The index event (IE) was defined as the first paid or denied FFS claim in the evaluation window. For members with paid and denied claims on the same day, the IE was classified as paid. For each member, the baseline period was defined as the 6 months prior to the IE (exclusive of the IE).

Inclusion Criteria:

1. At least one FFS paid claim for pregabalin during the evaluation window OR
2. At least one FFS denied claim for pregabalin during the evaluation window associated with either error 3002 (NDC requires PA) or error 3000 (units exceed authorized units on pa master file) AND NOT associated with any of the error codes indicating non-coverage through FFS or billing errors (**Appendix 1**).

Exclusion Criteria:

1. Primary insurance coverage (i.e., third party liability [TPL]) at any time during the baseline period;
2. Individuals with Medicare Part D coverage or limited or no Medicaid drug benefit at any time during the baseline period. Claims data for these patients may be incomplete. Patients were identified based on the following benefit packages:

Category	Benefit Package	Description

Medicare Part D coverage	BMM BMD MED	Qualified Medicare Beneficiary + Oregon Health Plan with Limited Drug Oregon Health Plan with Limited Drug Qualified Medicare Beneficiary
Limited or no Medicaid drug benefit	MND CWM SMF SMB	Transplant package Citizenship Waived Emergency Medical Special Low-Income Medicare Beneficiary Only Special Low-Income Medicare Beneficiary Only

3. Non-continuous Medicaid eligibility during the baseline period

Outcomes evaluated in this analysis included:

- Number of members with an FDA-approved or pre-specified off-label diagnosis for pregabalin based on ICD-10 codes on medical claims during the baseline period or on the index date.
- Prescriber type defined based on taxonomy associated with the IE.
- Number of members with a GAD diagnosis and recent claims for an SSRI or SNRI.

Results:

A total of 438 people were identified who had paid or denied claims for pregabalin from 7/1/21 to 6/30/22. After application of exclusion criteria which removed any members who may have had incomplete claims data, 180 members (41.1%) were included in the analysis.

Demographics for members with paid or denied claims for pregabalin are listed in **Table 1**. Prior authorization is currently required for all forms of pregabalin, and the first claim for most people was denied (79%). Only a small percentage (15.6%) had recent claims for pregabalin in the 6 months prior to their first identified claim. People with prior therapy for pregabalin were more likely to have a paid claim in the evaluation window which would be expected for members with an approved PA already on file. The majority of people with claims for pregabalin were adults (>95%) who identified as female (64%). About 65% of people with claims for pregabalin were American Indians or Alaskan Natives, and about 28% of people identified as White.

Less than half of members (48%) had an FDA-approved diagnosis present in their recent medical claims (**Table 2**). In members without an FDA-approved diagnosis, about 22% of members had a diagnosis in medical claims indicative of an off-label indication referenced in compendia where evidence may favor efficacy. Chronic pain conditions and other types of anxiety (such as social anxiety disorder or panic disorder) without evidence for use of pregabalin were present in 31% of members. The most common diagnoses identified in medical claims for members with claims for pregabalin included diabetic neuropathy or diabetes (29%), other neuropathies and nerve injury (14%), and fibromyalgia (17%). A diagnosis of GAD was present for 14% of patients (n=26). Comorbid diagnoses were common in people with GAD, and 14 people (54%) with a diagnosis of GAD also had another FDA-approved diagnosis in the 6 months prior to their first claim.

Because this analysis evaluated only the first claim in the reporting period, there are limited conclusions which can be drawn from the proportion of paid and denied claims. An initial denied claim for pregabalin likely correlates to a delay in care or a shift in costs to the patient, but the extent of this delay and cost was not quantified with this analysis. Compared to members with initial denied claims, initial paid claims were more common for members with FDA-approved and funded indications of diabetes (35% vs. 27%) and epilepsy (27% vs. 1%). Denied claims were more common for people with diagnosis of GAD (22 of 26 people; 84%) and other off-label conditions without evidence for use such as other chronic or nonspecific pain, migraine, and other anxiety disorders.

Common first-line treatments for GAD include SSRIs or SNRIs. Some SSRIs and SNRIs are also used for treatment of fibromyalgia, chronic pain, and neuropathies. In people with a diagnosis of GAD, less than half of members had a paid claim for a SSRI or SNRI in the prior 35 days (**Table 3**). Use of SSRIs and SNRIs was even less common in people without a GAD diagnosis.

General practitioners accounted for the majority of pregabalin claims (**Table 4**). The most common prescribers included family medicine physicians, family nurse practitioners, internal medicine physicians, and physician assistants. About 6% of people (n=10) had prescriptions written from a neurologist and about 2% (n=4) had prescriptions written by a provider specializing in pain.

Table 1. Demographic Data of Members with Included FFS Pharmacy Claims.

	Paid IE		Denied IE		Total	
	37	%	143	%	180	%
Female	24	64.9%	92	64.3%	116	64.4%
Age (years) – mean (range)	44	(15-66)	46	(6-67)	45	(6-67)
<18	2	5.4%	1	0.7%	3	1.7%
18-35	8	21.6%	34	23.8%	42	23.3%
36-64	25	67.6%	104	72.7%	129	71.7%
>=65	2	5.4%	4	2.8%	6	3.3%
Race						
White	14	37.8%	36	25.2%	50	27.8%
Unknown	4	10.8%	14	9.8%	18	10.0%
American Indian/Alaskan Native (HNA)	19	51.4%	88	61.5%	107	59.4%
Other	0	0.0%	5	3.5%	5	2.8%
Therapy Type						
New start (no pregabalin claims in the prior 6 months)	12	32.4%	140	97.9%	152	84.4%
Continuation (pregabalin claims in the prior 6 months) *	25	67.6%	3	2.1%	28	15.6%

* Because people are categorized by their first paid or denied claim, no members with IEs after 1/1/2022 can be classified as "continuation" by definition

Table 2. Diagnoses Present in Medical Claims for Members with FFS Claims for Pregabalin

	Paid IE		Denied IE		Total	
	37	%	143	%	180	%
FDA-approved indication	**24**	**64.9%**	**62**	**43.4%**	**86**	**47.8%**
Diabetic neuropathy (or diabetes dx)	13	35.1%	39	27.3%	52	28.9%
Fibromyalgia (unfunded)	7	18.9%	24	16.8%	31	17.2%
Epilepsy	10	27.0%	1	0.7%	11	6.1%

Postherpetic neuralgia (or herpes zoster)	0	0.0%	1	0.7%	1	0.6%
Spinal cord injury pain	0	0.0%	1	0.7%	1	0.6%
Off-label with some evidence for use*	**5**	**13.5%**	**34**	**23.8%**	**39**	**21.7%**
Other neuropathies and nerve injury	5	13.5%	20	14.0%	25	13.9%
Generalized anxiety disorder (GAD)	0	0.0%	12	8.4%	12	6.7%
Restless leg syndrome (unfunded)	0	0.0%	3	2.1%	3	1.7%
Post-operative pain (acute)	0	0.0%	2	1.4%	2	1.1%
Uremic pruritus	0	0.0%	1	0.7%	1	0.6%
Vasomotor menopause symptoms	0	0.0%	0	0.0%	0	0.0%
None of the Above	**8**	**21.6%**	**47**	**32.9%**	**55**	**30.6%**
Other common pain conditions						
Chronic pain	2	5.4%	17	11.9%	19	10.6%
Dorsalgia	1	2.7%	22	15.4%	23	12.8%
Spinal Disc Disorders	0	0.0%	9	6.3%	9	5.0%
Joint Pain	0	0.0%	7	4.9%	7	3.9%
Extremity Pain	1	2.7%	4	2.8%	5	2.8%
Osteoarthritis	0	0.0%	4	2.8%	4	2.2%
Migraine	0	0.0%	4	2.8%	4	2.2%
Cancer pain	0	0.0%	1	0.7%	1	0.6%
Other anxiety disorders	2	5.4%	14	9.8%	16	8.9%

*Off-label conditions with some evidence were identified based on compendia-support indicating evidence may favor efficacy[9,10]

Note: Categories are mutually exclusive and members were excluded from subsequent categories if they had a diagnosis in a previous group.

Table 3. Previous therapy with an SSRI or SNRI in the 35 days before the IE

	Paid IE		Denied IE		Total	
	37	%	143	%	180	%
GAD Diagnosis	4		22		26	
SSRI/SNRI	3	75.00%	9	40.91%	12	46.15%
No SSRI/SNRI	1	25.00%	13	59.09%	14	53.85%
No GAD Diagnosis	33		121		154	

SSRI/SNRI	11	33.33%	24	19.83%	35	22.73%
No SSRI/SNRI	22	66.67%	97	80.17%	119	77.27%

Table 4. Most common prescribing providers for pregabalin

			Paid IE		Denied IE		Total	
			37	%	143	%	180	%
	Taxonomy	**Description**						
1	207Q00000X	PHYSICIAN-FAMILY MEDICINE	9	24.3%	38	26.6%	47	26.1%
2	363LF0000X	NURSE PRACTITIONER - FAMILY	10	27.0%	31	21.7%	41	22.8%
3	207R00000X	PHYSICIAN-INTERNAL MEDICINE	3	8.1%	14	9.8%	17	9.4%
4	363A00000X	PHYSICIAN ASSISTANT	1	2.7%	14	9.8%	15	8.3%
5	363AM0700X	PHYSICIAN ASSISTANT - MEDICAL	2	5.4%	10	7.0%	12	6.7%
6	2084N0400X	PHYSICIAN-PSYCHIATRY&NEUROLOGY-NEUROLOGY	3	8.1%	7	4.9%	10	5.6%
7	363L00000X	NURSE PRACTITIONER	2	5.4%	7	4.9%	9	5.0%
8	363LA2200X	NURSE PRACTITIONER - ADULT HEALTH	0	0.0%	3	2.1%	3	1.7%
9	2081P2900X	PHYSICIAN-PHYSICAL MEDICINE&REHAB-PAIN MEDICINE	0	0.0%	2	1.4%	2	1.1%
10	390200000X	STUDENT IN AN ORGANIZED HEALTH CARE EDUCATION/TRAINING PROGRAM	1	2.7%	1	0.7%	2	1.1%
11	363LW0102X	NURSE PRACTITIONER - WOMEN'S HEALTH	1	2.7%	1	0.7%	2	1.1%
12	213ES0103X	PODIATRIST - SURGERY	0	0.0%	2	1.4%	2	1.1%
13	208VP0014X	PHYSICIAN-PAIN MEDICINE-INTERVENTIONAL PAIN MEDICINE	0	0.0%	2	1.4%	2	1.1%
14	208100000X	PHYSICIAN-PHYSICAL MEDICINE&REHAB	0	0.0%	2	1.4%	2	1.1%

Limitations and Discussion:

- The goal of this analysis was to evaluate diagnoses for OHP FFS members prescribed pregabalin. Overall, less than half of people with claims for pregabalin had an FDA-approved diagnosis. A diagnosis of GAD was present in the medical claims for 14% of people (n=26) with claims for pregabalin. However, it is difficult to discern the exact indication for which pregabalin was prescribed based on claims data alone. Fourteen people (54%) with a diagnosis of GAD also had another FDA-approved diagnosis in the 6 months prior to their first claim, and less than half of people with a diagnosis of GAD were prescribed first-line therapy with an SSRI or SNRI (46%).
- One limitation of this analysis is that we categorized people according to the first claim in the evaluation window and did not evaluate what proportion of members with an initial denial ultimately had a PA approved. Therefore, there are limited conclusions which can be drawn from the proportion of paid and denied claims. An initial denied claim for pregabalin likely correlates to a delay in care or a shift in costs to the patient, but the extent of this delay and cost was not quantified with this analysis. In the third quarter of 2022, about 18% of people had an initial paid claim for pregabalin, 15% of people with an initial denial had pregabalin subsequently covered by FFS within 90 days, 15% switched therapy to a different antiepileptic (such as gabapentin), and 51% did not have any paid claims for antiepileptics within the 90 days following the initial denial. The most common reasons for lack of follow-up claims included people who transitioned into a CCO who may have covered pregabalin (27%), people with other insurance on file which may have been billed (36%), and people without a PA submitted by the provider (27%).

- There are other inherent limitations with use of claims data including use of diagnostic data based on claims history which may be incomplete or not accurately reflect true patient diagnoses. Diagnostic data was evaluated only over a 6 month period, and diagnoses for members on stable maintenance therapy may be missed if they had infrequent provider visits.
- A significant proportion of people identified with paid FFS claims for pregabalin were ineligible for inclusion in this study because of exclusion criteria (59%). This study assumes that included members are still representative of the entire Medicaid population.
- A relatively short duration (35 days) was used to quantify recent treatment with an SSRI or SNRI. Members may have been categorized incorrectly if they had any missed doses or did not fill their prescription on time.

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Appendix 1: Drug Coding

Table A1. Error codes associated with denied claims that were excluded from the analysis

Error Code	Description
2017	RECIPIENT SERVICES COVERED BY HMO PLAN
4999	THIS DRUG IS COVERED BY MEDICARE PART D

576	CLAIM HAS THIRD-PARTY PAYMENT
2508	RECIPIENT COVERED BY PRIVATE INSURANCE (PHARMACY)
2002	RECIPIENT NOT ELIGIBLE FOR HEADER DATE OF SERVICE
643	INVALID OTHER COVERAGE CODE
3343	Questionable TPL amount
628	Other Coverage Reject Code Required for OCC 3
505	THIRD PARTY PAYMENT AMOUNT MORE THAN CLAIM CHARGE
513	RECIPIENT NAME AND NUMBER DISAGREE
238	RECIPIENT NAME IS MISSING
2809	DOB IS INVALID
2808	DOB IS MISSING
219	QUANTITY DISPENSED IS MISSING
1000	BILLING PROVIDER ID NOT ON FILE
1040	PRESCRIBING PHYSICIAN NOT ENROLLED
1026	PRESCRIBING PHYSICIAN ID NOT ON FILE
205	PRESCRIBING PROVIDER ID MISSING

Table A2. Diagnoses codes associated with FDA-approved or off-label indications

Description	**ICD-10 code(s)**
FDA-approved indication	
Diabetic neuropathy (or diabetes dx)	E08x-E13x
Postherpetic neuralgia (or herpes zoster)	B02x
Fibromyalgia (unfunded)	M797
Epilepsy	G40x
Spinal cord injury pain	S14x, S24x, S34x
Off-label with some evidence for use	
Other neuropathies and nerve injury	see **Table A3**
Post-operative pain (acute)	G891x
Uremic pruritus	L29x, N185x-N186x, Z992
Restless leg syndrome (unfunded)	G2581
Generalized anxiety disorder (GAD)	F411x
Vasomotor menopause symptoms	N95x
None of the above	
Other common pain conditions	

- Chronic pain	G892x, G894
- Dorsalgia	M54x
- Spinal Disc Disorders	M50x-M53x
- Extremity Pain	M796x
- Joint Pain	M255x
- Cancer pain	G893
- Migraine	G43x
- Osteoarthritis	M15x-M19x
Other anxiety disorders	F410x, F413x-F419x

Table A3. Diagnosis codes associated with neuropathy or nerve injury

Description	**ICD-10 code(s)**
Tuberculous neuritis	A1783
Diphtheritic polyneuritis	A3683
Meningococcal retrobulbar neuritis	A3982
Late congenital syphilitic polyneuropathy	A5043
Late congenital syphilitic optic nerve atrophy	A5044
Late syphilitic neuropathy	A5215
Mumps polyneuropathy	B2684
Gammaherpesviral mononucleosis with polyneuropathy	B2701
Cytomegaloviral mononucleosis with polyneuropathy	B2711
Other infectious mononucleosis with polyneuropathy	B2781
Infectious mononucleosis, unspecified with polyneuropathy	B2791
Systemic atrophies primarily affecting central nervous system in diseases classified elsewhere	G13x
Disorders of trigeminal nerve	G50x
Facial nerve disorders	G51x
Disorders of other cranial nerves	G52x
Cranial nerve disorders in diseases classified elsewhere	G53x
Nerve root and plexus disorders	G54x
Nerve root and plexus compressions in diseases classified elsewhere	G55x
Mononeuropathies of upper limb	G56x
Mononeuropathies of lower limb	G57x
Other mononeuropathies	G58X
Mononeuropathy in diseases classified elsewhere	G59x
Hereditary and idiopathic neuropathy	G60x

Inflammatory polyneuropathy	G61x
Other and unspecified polyneuropathies	G62x
Polyneuropathy in diseases classified elsewhere	G63x
Sequelae of inflammatory and toxic polyneuropathies	G65x
Idiopathic peripheral autonomic neuropathy	G90x
Rheumatoid polyneuropathy with rheumatoid arthritis	M055x
Systemic sclerosis with polyneuropathy	M3483
Neuralgia and neuritis, unspecified	M792
Injury of cranial nerve	S04x
Injury of nerves at shoulder and upper arm level	S44x
Injury of nerves at forearm level	S54x
Injury of nerves at wrist and hand level	S64x
Injury of nerves at hip and thigh level	S74x
Injury of nerves at lower leg level	S84x
Injury of nerves at ankle and foot level	S94x
Other specified myoneural disorders	G7089
Myoneural disorder, unspecified	G709

Table A4. Drug coding and definitions for SSRIs and SNRIs

HIC3	HSN	Generic
H2S	001655	fluoxetine HCl
H2S	006324	sertraline HCl
H2S	006338	fluvoxamine maleate
H2S	007344	paroxetine HCl
H2S	010321	citalopram hydrobromide
H2S	024022	escitalopram oxalate
H2S	025796	paroxetine mesylate
H7C	008847	venlafaxine HCl
H7C	026521	duloxetine HCl
H7C	035420	desvenlafaxine succinate
H7C	040202	desvenlafaxine
H7C	040632	levomilnacipran HCl
H7C	048091	venlafaxine besylate
H7Z	025800	olanzapine/fluoxetine HCl
H8P	037597	vilazodone HCl
H8T	040637	vortioxetine hydrobromide

Pregabalin

Goal(s):
- Provide coverage only for funded diagnoses that are supported by the medical literature.

Length of Authorization:
- 90 days to lifetime (criteria-specific)

Requires PA:
- Pregabalin and pregabalin extended release

Covered Alternatives
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Approval Criteria		
1. Is this a request for renewal of a previously approved prior authorization for pregabalin?	**Yes**: Go to **Renewal Criteria**	**No**: Go to # 2
2. What diagnosis is being treated?	Record ICD10 code	
3. Is the request for pregabalin immediate release?	**Yes:** Go to #4	**No:** Go to #5
4. Does the patient have a diagnosis of epilepsy?	**Yes:** Approve for lifetime	**No:** Go to #5
5. Is the request for an OHP-funded diagnosis ?	**Yes:** Go to #7	**No:** For current age ≥ 21 years: Pass to RPh. Deny; not funded by the OHP. For current age < 21 years: Go to #6

Approval Criteria		
6. Is there documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc)?	**Yes**: Go to #7	**No:** Pass to RPh; Deny; medical necessity.
7. Is the request for an FDA-approved or evidence-supported diagnosis (see Table 1 below for examples)?	**Yes:** Go to #8	**No:** Pass to RPh. Deny; medical appropriateness.
8. Has the patient tried and failed, or have contraindications or intolerance to, gabapentin therapy for 90 days?	**Yes**: Approve for 90 days	**No:** Pass to RPh. Deny; medical appropriateness. Recommend trial of gabapentin for 90 days

Renewal Criteria		
1. Does the patient have documented improvement from pregabalin?	**Yes**: Approve for up to 12 months	No: Pass to RPh. Deny; medical appropriateness

Table 1. Pregabalin formulations for specific indications based on available evidence

Condition	Pregabalin	Pregabalin Extended-Release
Funded		
Diabetic Neuropathy	X	X
Postherpetic Neuropathy	X	X
Painful Polyneuropathy	X	
Spinal Cord Injury Pain	X	
Chemotherapy Induced Neuropathy	X	
Non-funded		
Fibromyalgia	X	

P&T Review: *4/23; 10/22 (SF); 10/21 (DM); 10/20; 1/19; 7/18; 3/18; 3/17*
Implementation: *10/1/18; 8/15/18; 4/1/17*