

Reference number(s) 178-C, REG 2814-C

# Initial Prior Authorization with Quantity Limit Provigil Narcolepsy Agents

# **Products Referenced by this Document**

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Provigil	modafinil

# **Indications**

### **FDA-approved Indications**

Provigil is indicated to improve wakefulness in adult patients with excessive sleepiness associated with narcolepsy, obstructive sleep apnea (OSA), or shift work disorder (SWD).

### Limitations of Use

In OSA, Provigil is indicated to treat excessive sleepiness and not as treatment for the underlying obstruction. If continuous positive airway pressure (CPAP) is the treatment of choice for a patient, a maximal effort to treat with CPAP for an adequate period of time should be made prior to initiating and during treatment with Provigil for excessive sleepiness.

# Compendial Uses

Fatigue related to multiple sclerosis<sup>8,9</sup>

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Idiopathic hypersomnia<sup>6</sup>

# **Coverage Criteria**

# Idiopathic Hypersomnia

Authorization may be granted when the requested drug is being prescribed for idiopathic hypersomnia when ALL of the following criteria are met:

- The requested drug is being prescribed by, or in consultation with, a sleep specialist.
- The patient has experienced the presence of daytime lapses into sleep or daily irrepressible periods of need to sleep for at least 3 months.
- Insufficient sleep syndrome has been ruled out such as by lack of improvement of sleepiness after an adequate trial of increased nocturnal time in bed, preferably confirmed by at least a week of sleep log with wrist actigraphy.
- A multiple sleep latency test (MSLT) documented fewer than two sleep onset rapid eye
  movement periods (SOREMPs) or no SOREMPs if the rapid eye movement (REM) latency on the
  preceding polysomnogram was less than or equal to 15 minutes.
- Sleep lab evaluation showed at least ONE of the following: mean sleep latency on MLST of less than or equal to 8 minutes, total 24-hour sleep time of greater than or equal to 660 minutes on 24-hour polysomnographic monitoring after correcting any chronic sleep deprivation or by wrist actigraphy in association with a sleep log and averaged over at least 7 days of unrestricted sleep.
- The patient does NOT have cataplexy.
- Hypersomnolence or MSLT results are not better explained by ANY of the following: another sleep disorder, other medical or psychiatric disorder, use of drugs or medications.

# Multiple Sclerosis-Related Fatigue

Authorization may be granted when the requested drug is being prescribed for multiple sclerosis-related fatigue.

### **Narcolepsy**

Authorization may be granted for a diagnosis of excessive sleepiness associated with narcolepsy when ALL of the following criteria are met:

- The requested drug is being prescribed by, or in consultation with, a sleep specialist.
- The diagnosis is confirmed by sleep study.

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# Obstructive Sleep Apnea (OSA)

Authorization may be granted for a diagnosis of excessive sleepiness associated with obstructive sleep apnea (OSA) when ALL of the following criteria are met:

- The requested drug is being prescribed by, or in consultation with, a sleep specialist.
- The diagnosis has been confirmed by polysomnography or home sleep apnea test (HSAT) with a technically adequate device.
- The patient has been receiving treatment for the underlying airway obstruction (continuous positive airway pressure [CPAP] or bilevel positive airway pressure [BIPAP]) for at least one month.
- The patient will continue to use CPAP or BIPAP after the requested drug is started.

# Shift Work Disorder (SWD)

Authorization may be granted for a diagnosis of excessive sleepiness associated with shift work disorder (SWD) when ALL of the following criteria are met:

- The requested drug is being prescribed by, or in consultation with, a sleep specialist.
- A sleep log and actigraphy monitoring have been completed for at least 14 days AND show a disrupted sleep and wake pattern.
- Symptoms have been present for 3 or more months.

# **Continuation of Therapy**

# Idiopathic Hypersomnia

Authorization may be granted when the requested drug is being prescribed for idiopathic hypersomnia when the following criteria is met:

The patient has achieved or maintained a positive response to treatment from baseline.

### Multiple Sclerosis-Related Fatigue

Authorization may be granted when the requested drug is being prescribed for multiple sclerosis-related fatigue when the following criteria is met:

The patient has achieved or maintained a positive response to treatment from baseline.

# Narcolepsy

Authorization may be granted for a diagnosis of excessive sleepiness associated with narcolepsy when the following criteria is met:

The patient has achieved or maintained a positive response to treatment from baseline.

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# Obstructive Sleep Apnea (OSA)

Authorization may be granted for a diagnosis of excessive sleepiness associated with obstructive sleep apnea (OSA) when ALL of the following criteria are met:

- The patient has achieved or maintained a positive response to treatment from baseline.
- The patient is compliant with using continuous positive airway pressure (CPAP) or bilevel positive airway pressure (BIPAP).

# Shift Work Disorder (SWD)

Authorization may be granted for a diagnosis of excessive sleepiness associated with shift work disorder (SWD) when ALL of the following criteria are met:

- The patient has achieved or maintained a positive response to treatment from baseline.
- The patient is still a shift-worker.

# **Quantity Limits Apply**

60 tablets per 25 days or 180 tablets per 75 days

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

# **Duration of Approval (DOA)**

178-C: DOA: 12 months2814-C: DOA: 12 months

# References

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- 8. Maski K, Trotti LM, Kotagal S, et al. Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine clinical practice guideline. J Clin Sleep Med. 2021;17(9):1881-1893.
- 9. Maski K, Trotti LM, Kotagal S, et al. Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine systematic review, meta-analysis, and GRADE assessment. J Clin Sleep Med. 2021;17(9):1895-1945.
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- 11. Shangyan H, Kuiqing L, Yumin X, et al. Meta-analysis of the efficiency of modafinil versus placebo in the treatment of multiple sclerosis fatigue. Mult Scler Relat Disord. 2018;19:85-89.
- 12. Trotti LM, Becker LA, Friederich Murray C, et al. Medications for daytime sleepiness in individuals with idiopathic hypersomnia. Cochrane Database Syst Rev. 2021;5(5):CD012714.

# **Document History**

Written by: UM Development (LS)

Date Written: 02/1999

Revised: 08/1999; 08/2000; UM Development (JG) 12/2002; (MG) 01/2004; (JG) 02/2004; (EI) 05/2005; (NB) 01/2006, 05/2006; (AM) 03/2007, 05/2008; (SE) 05/2009; (MS) 10/2009; (SE) 09/2010, ) 07/2011 (revised criteria to be consistent with CMS submission/created Medicare and non-Medicare versions (MDC-2 09-2010)); (MS) 08/2011, 06/2012; (RP) 04/2013; (CT) 09/2013 (CMS requested changes), 12/2013 (rephrased SWD), (PL) 05/2014 (SF) 05/2015, 05/2016 (no clinical changes); (CT) 06/2016 (created separate Med D); (SF) 05/2017, 04/2018 (no clinical changes), 03/2019 (no clinical changes); (KC) 03/2020 (added QL, question changes, removed MDC designation from title/document), 03/2021 (combined 178-C and 2814-C into one document), (MRS) 03/2022 (added prescriber restriction for FDA approved indications, added coverage criteria for continuation in narcolepsy, added to coverage criteria for initiation and continuation in SWD, added ongoing PAP requirement for initiation and continuation in OSA, added compendial use of idiopathic hypersomnia), 03/2023 (added coverage criteria for continuation in MS-related fatigue), (NS/TM) 01/2024 (no clinical changes); KMB/ASA 12/2024 (added HSAT to OSA)

Reviewed: CRC 2/1999, 8/1999, 09/2000; 12/2002; 02/2004; CDPR/Medical Affairs (MM) 06/2005, 01/2006, 05/2006; (WLF) 03/2007, 05/2008, 05/2009, 10/2009; (KP) 09/2010, 08/2011, 06/2012; (LB) 05/2013; (DNC) 09/2013, 12/2013, (DNC) 05/2014 (KRU) 05/2015; (CHART) 03/26/20, 03/25/21, 03/31/2022, 08/11/2022, 03/30/2023, 12/21/2023, 12/19/2024, 01/02/2025, 01/23/2025

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External Review: 02/2001; 02/2003; 04/2004; 11/2005, 06/2006, 08/2007, 10/2008, 05/2009, 12/2010, 10/2011, 10/2012, 08/2013, 12/2013, 08/2014, 08/2015, 08/2016, 08/2017, 08/2018, 08/2019, 08/2020, 08/2021, 08/2022, 08/2023, 04/2024, 04/2025

CRIT	ERIA FOR APPROVAL		
1	Does the patient have a diagnosis of excessive sleepiness associated with obstructive sleep apnea (OSA)? [If Yes, then go to 2. If No, then go to 9.]	Yes	No
2	Is this request for continuation of therapy? [If Yes, then go to 3. If No, then go to 5.]	Yes	No
3	Has the patient achieved or maintained a positive response to treatment from baseline? [If Yes, then go to 4. If No, then no further questions.]	Yes	No
4	Is the patient compliant with using continuous positive airway pressure (CPAP) or bilevel positive airway pressure (BIPAP)? [If Yes, then go to 34. If No, then no further questions.]	Yes	No
5	Is the requested drug being prescribed by, or in consultation with, a sleep specialist? [If Yes, then go to 6. If No, then no further questions.]	Yes	No
6	Is the diagnosis confirmed by polysomnography or home sleep apnea test (HSAT) with a technically adequate device? [If Yes, then go to 7. If No, then no further questions.]	Yes	No
7	Has the patient been receiving treatment for the underlying airway obstruction (continuous positive airway pressure [CPAP] or bilevel positive airway pressure [BIPAP]) for at least one month? [If Yes, then go to 8. If No, then no further questions.]	Yes	No
8	Will the patient continue to use continuous positive airway pressure (CPAP) or bilevel positive airway pressure (BIPAP) after the requested drug is started? [If Yes, then go to 34. If No, then no further questions.]	Yes	No
9	Does the patient have a diagnosis of excessive sleepiness associated with narcolepsy? [If Yes, then go to 10. If No, then go to 14.]	Yes	No

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10	Is this request for continuation of therapy? [If Yes, then go to 11. If No, then go to 12.]	Yes	No
11	Has the patient achieved or maintained a positive response to treatment from baseline?	Yes	No
	[If Yes, then go to 34. If No, then no further questions.]		
12	Is the requested drug being prescribed by, or in consultation with, a sleep specialist? [If Yes, then go to 13. If No, then no further questions.]	Yes	No
13	Is the diagnosis confirmed by a sleep study? [If Yes, then go to 34. If No, then no further questions.]	Yes	No
14	Does the patient have a diagnosis of excessive sleepiness associated with Shift Work Disorder (SWD)? [If Yes, then go to 15. If No, then go to 21.]	Yes	No
15	Is this request for continuation of therapy? [If Yes, then go to 16. If No, then go to 18.]	Yes	No
16	Has the patient achieved or maintained a positive response to treatment from baseline? [If Yes, then go to 17. If No, then no further questions.]	Yes	No
17	Is the patient still a shift-worker?	Yes	No
''	[If Yes, then go to 34. If No, then no further questions.]	103	140
18	Is the requested drug being prescribed by, or in consultation with, a sleep specialist?	Yes	No
	[If Yes, then go to 19. If No, then no further questions.]		
19	Has a sleep log and actigraphy monitoring been completed for at least 14 days AND shows a disrupted sleep and wake pattern? [If Yes, then go to 20. If No, then no further questions.]	Yes	No
20	Have the patient's symptoms been present for 3 or more months? [If Yes, then go to 34. If No, then no further questions.]	Yes	No
21	Is the requested drug being prescribed for idiopathic hypersomnia? [If Yes, then go to 22. If No, then go to 31.]	Yes	No

22	Is this request for continuation of therapy? [If Yes, then go to 23. If No, then go to 24.]	Yes	No
23	Has the patient achieved or maintained a positive response to treatment from baseline?	Yes	No
	[If Yes, then go to 34. If No, then no further questions.]		
24	Is the requested drug being prescribed by, or in consultation with, a sleep specialist? [If Yes, then go to 25. If No, then no further questions.]	Yes	No
25	Has the patient experienced the presence of daytime lapses into sleep or daily irrepressible periods of need to sleep for at least 3 months? [If Yes, then go to 26. If No, then no further questions.]	Yes	No
26	Has insufficient sleep syndrome been ruled out, such as by lack of improvement of sleepiness after an adequate trial of increased nocturnal time in bed, preferably confirmed by at least a week of sleep log with wrist actigraphy? [If Yes, then go to 27. If No, then no further questions.]	Yes	No
27	Has a multiple sleep latency test (MSLT) documented fewer than two sleep onset rapid eye movement periods (SOREMPs) or no SOREMPs if the rapid eye movement (REM) latency on the preceding polysomnogram was less than or equal to 15 minutes? [If Yes, then go to 28. If No, then no further questions.]	Yes	No
28	Has sleep lab evaluation shown at least ONE of the following: A) mean sleep latency on multiple sleep latency test (MLST) of less than or equal to 8 minutes, B) total 24-hour sleep time of greater than or equal to 660 minutes on 24-hour polysomnographic monitoring after correcting any chronic sleep deprivation or by wrist actigraphy in association with a sleep log and averaged over at least 7 days of unrestricted sleep? [If Yes, then go to 29. If No, then no further questions.]	Yes	No
29	Does the patient have cataplexy? [If Yes, then no further questions. If No, then go to 30.]	Yes	No
30	Are the patient's hypersomnolence or multiple sleep latency test (MSLT) results better explained by ANY of the following: A) another sleep disorder, B) other medical or psychiatric disorder, C) use of drugs or medications? [If Yes, then no further questions. If No, then go to 34.]	Yes	No

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31	Is the requested drug being prescribed for multiple sclerosis-related fatigue? [If Yes, then go to 32. If No, then no further questions.]	Yes	No
32	Is the request for continuation of therapy? [If Yes, then go to 33. If No, then go to 34.]	Yes	No
33	Has the patient achieved or maintained a positive response to treatment from baseline? [If Yes, then go to 34. If No, then no further questions.]	Yes	No
34	Does the patient require MORE than the plan allowance of 60 tablets per month? [No further questions]	Yes	No
	RPH Note: If yes, then deny and enter a partial approval for 60 tablets / 25 days or 180 tablets / 75 days.		

	Mapping Instructions			
	Yes	No	DENIAL REASONS	
1.	Go to 2	Go to 9		
2.	Go to 3	Go to 5		
3.	Go to 4	Deny	Your plan only covers this drug if it works well for you. We have denied your request because the drug did not work well for you. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.  [Short Description: Continuation: Efficacy]	
4.	Go to 34	Deny	Your plan only covers this drug if you are using it with treatment for airway problems due to obstructive sleep apnea. We have denied your request because you are not using it with treatment for airway problems due to obstructive sleep apnea. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For	

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			this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.  [Short Description: Continuation: Not on required concurrent therapy with PAP]
5.	Go to 6	Deny	Your plan only covers this drug if your doctor is a sleep specialist or has talked about your care plan with a sleep specialist. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.  [Short Description: Prescriber specialty]
6.	Go to 7	Deny	Your plan only covers this drug when you have a sleep test that shows obstructive sleep apnea (OSA). We denied your request because we did not receive your results, or your test result did not show obstructive sleep apnea (OSA). We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.  [Short Description: Lab/test for OSA]
7.	Go to 8	Deny	Your plan only covers this drug if you have been using treatment for airway problems due to obstructive sleep apnea for at least one month. We have denied your request because you have not been using treatment for airway problems due to obstructive sleep apnea for one month. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.

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			[Short Description: Not on required concurrent therapy with PAP for 1 month]
8.	Go to 34	Deny	Your plan only covers this drug if you will be using it with treatment for airway problems due to obstructive sleep apnea. We have denied your request because you will not be using it with treatment for airway problems due to obstructive sleep apnea. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.  [Short Description: Not on required concurrent therapy with PAP]
9.	Go to 10	Go to 14	
10.	Go to 11	Go to 12	
11.	Go to 34	Deny	Your plan only covers this drug if it works well for you. We have denied your request because the drug did not work well for you. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.  [Short Description: Continuation: Efficacy]
12.	Go to 13	Deny	Your plan only covers this drug if your doctor is a sleep specialist or has talked about your care plan with a sleep specialist. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.  [Short Description: Prescriber specialty]
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13.	Go to 34	Deny	Your plan only covers this drug when you have a sleep lab test that shows narcolepsy. We denied your request because we did not receive your results, or your test result did not show narcolepsy. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.  [Short Description: Lab/test for narcolepsy]
14.	Go to 15	Go to 21	
15.	Go to 16	Go to 18	
16.	Go to 17	Deny	Your plan only covers this drug if it works well for you. We have denied your request because the drug did not work well for you. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.  [Short Description: Continuation: Efficacy]
17.	Go to 34	Deny	We have denied your request because your plan does not cover this drug if you are no longer a shift worker. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.  [Short Description: Exclusion, No longer shift worker]
18.	Go to 19	Deny	Your plan only covers this drug if your doctor is a sleep specialist or has talked about your care plan with a sleep specialist. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can

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			request the drug policy for more details. You can also request other plan documents for your review.  [Short Description: Prescriber specialty]
19.	Go to 20	Deny	Your plan only covers this drug when you have a sleep test that shows shift work disorder (SWD). We denied your request because we did not receive your results, or your test result did not show shift work disorder (SWD). We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.  [Short Description: Lab/test for SWD]
20.	Go to 34	Deny	Your plan only covers this drug if you have had symptoms for 3 or more months. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.  [Short Description: Disease duration]
21.	Go to 22	Go to 31	
22.	Go to 23	Go to 24	
23.	Go to 34	Deny	Your plan only covers this drug if it works well for you. We have denied your request because the drug did not work well for you. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.  [Short Description: Continuation: Efficacy]

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24.	Go to 25	Deny	Your plan only covers this drug if your doctor is a sleep specialist or has talked about your care plan with a sleep specialist. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.  [Short Description: Prescriber specialty]
25.	Go to 26	Deny	Your plan only covers this drug if you have had symptoms for 3 or more months. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.  [Short Description: Disease duration]
26.	Go to 27	Deny	Your plan only covers this drug when you have had certain sleep tests that show idiopathic hypersomnia (IH). We denied your request because we did not receive your results, or your test result did not show IH. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.  [Short Description: Lab/test for IH]
27.	Go to 28	Deny	Your plan only covers this drug when you have had certain sleep tests that show idiopathic hypersomnia (IH). We denied your request because we did not receive your results, or your test result did not show IH. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more

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			details. You can also request other plan documents for your review.  [Short Description: Lab/test for IH]
28.	Go to 29	Deny	Your plan only covers this drug when you have had certain sleep tests that show idiopathic hypersomnia (IH). We denied your request because we did not receive your results, or your test result did not show IH. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.  [Short Description: Lab/test for IH]
29.	Deny	Go to 30	We have denied your request because your plan does not cover this drug if you have cataplexy. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.  [Short Description: Exclusion for IH, Cataplexy]
30.	Deny	Go to 34	We have denied your request because your plan does not cover this drug if you have symptoms caused by another disease or drug. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.  [Short Description: Exclusion for IH, Alternate cause]
31.	Go to 32	Deny	Your plan only covers this drug when it is used for certain health conditions. Covered uses are: A) Obstructive sleep apnea (OSA), B)

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		Narcolepsy, C) Shift work disorder (SWD), D) Idiopathic hypersomnia, and E) Multiple sclerosis-related fatigue. Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.  [Short Description: Diagnosis]
Go to 33	Go to 34	
Go to 34	Deny	Your plan only covers this drug if it works well for you. We have denied your request because the drug did not work well for you. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.  [Short Description: Continuation: Efficacy]
Deny	[PA approved for 12 months. Approve 60 tablets / 25 days or 180 tablets / 75 days.]. Approve, 12 Months	We have denied your request because it is for more than the amount your plan covers (quantity limit). We reviewed the information we had. We have partially approved your request for this drug up to the amount your plan covers (60 tablets per month). Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.  [Short Description: Quantity, Exceeds max limit, Partial denial]
	Go to 34	Deny  [PA approved for 12 months. Approve 60 tablets / 25 days or 180 tablets / 75 days.]. Approve, 12