Gabapentin ER (extended-release) Quantity Limit Program Summary

Quantity limits apply to Medicaid only.

POLICY REVIEW CYCLE

Effective Date	Date of Origin
07-01-2024	02-01-2012

FDA APPROVED INDICATIONS AND DOSAGE

See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm

POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Gralise	gabapentin (once-daily) tab	450 MG	30	Tablets	30	DAYS	Gralise dosage must be titrated up over 15 days	1. The patient requires increased quantities of Gralise to accommodate a titration schedule. The increased quantity will be approved for 1 month only.	
Gralise	gabapentin (once-daily) tab	750 MG	30	Tablets	30	DAYS	Gralise dosage must be titrated up over 15 days	1. The patient requires increased quantities of Gralise to accommodate a titration schedule. The increased quantity will be approved for 1 month only.	
Gralise	gabapentin (once-daily) tab	900 MG	60	Tablets	30	DAYS	Gralise dosage must be titrated up over 15 days	1. The patient requires increased quantities of Gralise to accommodate a titration	

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
								schedule. The increased quantity will be approved for 1 month only.	
Gralise	Gabapentin (Once-Daily) Tab 300 MG	300 MG	30	Tablets	30	DAYS	Gralise dosage must be titrated up over 15 days	1. The patient requires increased quantities of Gralise to accommodate a titration schedule. The increased quantity will be approved for 1 month only.	
Gralise	Gabapentin (Once-Daily) Tab 600 MG	600 MG	90	Tablets	30	DAYS	Gralise dosage must be titrated up over 15 days	1. The patient requires increased quantities of Gralise to accommodate a titration schedule. The increased quantity will be approved for 1 month only.	
Horizant	Gabapentin Enacarbil Tab ER 300 MG	300 MG	60	Tablets	30	DAYS			
Horizant	Gabapentin Enacarbil Tab ER 600 MG	600 MG	60	Tablets	30	DAYS			

ADDITIONAL QUANTITY LIMIT INFORMATION

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Additional QL Information	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
62540030000325	Gralise	gabapentin (once-daily) tab	450 MG	Gralise dosage must be titrated up over 15 days			
62540030000345	Gralise	gabapentin (once-daily) tab	750 MG	Gralise dosage must be titrated up over 15 days			
62540030000360	Gralise	gabapentin (once-daily) tab	900 MG	Gralise dosage must be titrated up over 15 days			
62540030000320	Gralise	Gabapentin (Once-Daily) Tab 300 MG	300 MG	Gralise dosage must be titrated up over 15 days			
62540030000330	Gralise	Gabapentin (Once-Daily) Tab 600 MG	600 MG	Gralise dosage must be titrated up over 15 days			

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Gralise	gabapentin (once-daily) tab	450 MG	Medicaid
Gralise	gabapentin (once-daily) tab	750 MG	Medicaid
Gralise	gabapentin (once-daily) tab	900 MG	Medicaid
Gralise	Gabapentin (Once-Daily) Tab 300 MG	300 MG	Medicaid
Gralise	Gabapentin (Once-Daily) Tab 600 MG	600 MG	Medicaid
Horizant	Gabapentin Enacarbil Tab ER 300 MG	300 MG	Medicaid
Horizant	Gabapentin Enacarbil Tab ER 600 MG	600 MG	Medicaid

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity Limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The patient requires increased quantities of Gralise to accommodate a titration schedule. The increased quantity will be approved for 1 month only **OR** 3. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. BOTH of the following: 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **OR** B. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** C. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **Length of Approval**: up to 12 months