

## NUSINERSEN / SPINRAZA GUIDELINE

### Medical Necessity

Gold Coast Health Plan (GCHP) considers nusinersen (Spinraza) medically necessary for persons with spinal muscular atrophy (SMA) who meet all of the following criteria:

- A. Member has SMA types I, II or III based on genetic testing;  
AND
- B. There is genetic documentation of 5q SMA homozygous gene mutation, homozygous gene deletion, or compound heterozygote;  
AND
- C. The medication is prescribed by or in consultation with a physician who specializes in treatment of spinal muscular atrophy.

### Continued Use of Nusinersen

Continued use of nusinersen is considered medically necessary for members who have responded to therapy, as demonstrated by maintenance or improvement in motor milestones.

### Experimental / investigational and not medically necessary

GCHP considers nusinersen experimental and investigational for all other indications.

### Dosage

The medically-necessary dosage of nusinersen is 12 mg (5 mL) per administration. Four loading doses of nusinersen are considered medically necessary for initiation of treatment. The first three loading doses are administered at 14-day intervals; the fourth loading dose is administered 30 days after the third dose. A maintenance dose is considered medically necessary once every four months thereafter.

### References

Spinal muscular atrophy from UpToDate.com. Available at: [https://www.uptodate.com/contents/spinal-muscular-atrophy?search=spinraza&source=search\\_result&selectedTitle=5~7&usage\\_type=default&display\\_rank=5](https://www.uptodate.com/contents/spinal-muscular-atrophy?search=spinraza&source=search_result&selectedTitle=5~7&usage_type=default&display_rank=5). Accessed April 6, 2020.

FDA Highlights of Prescribing Information. Available at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2016/209531lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/209531lbl.pdf). Accessed April 6, 2020.

MEDICAL ADVISORY COMMITTEE GUIDELINE HISTORY			
Adopted By MAC	Reapproved	Revised	Retired
April 25, 2018			
	April 25, 2019		
	April 23, 2020		