Market Applicability															
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**LA**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	N/A	N/A	X	N/A	X	X	X	X	X	X	N/A	N/A	X

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Mepsevii (vestronidase alfa)

DRUG.00116

Override(s)	Approval Duration
Prior Authorization	Initial therapy: 6 months Continuation therapy: 6 months

Medications
Mepsevii (vestronidase alfa-vjbk) intravenous solution

APPROVAL CRITERIA

Initial Therapy

Mepsevii (vestronidase alfa-vjbk) may be approved for the treatment of Mucopolysaccharidosis type VII when the following criteria are met:

I. Documentation of confirmatory diagnosis based on leukocyte or fibroblast glucuronidase enzyme assay or genetic testing; **AND**
II. Elevated urine glycosaminoglycans excretion at a minimum of 3-fold over the mean normal for age at screening.

Continuation Therapy

Continuation of treatment with Mepsevii (vestronidase alfa-vjbk) beyond 6 months after initiation of therapy, and every 6 months thereafter, may be approved for the treatment of Mucopolysaccharidosis type VII when the following criteria are met:

I. When initial therapy was determined to meet the above criteria; **AND**
II. When there is documentation of clinically significant improvement or stabilization in clinical signs and symptoms of disease compared to the predicted natural history trajectory of disease.

Mepsevii (vestronidase alfa-vjbk) may **not** be approved when criteria are not met and for all other indications.

State Specific Mandates		
State name N/A	Date effective N/A	Mandate details (including specific bill if applicable) N/A

Market Applicability															
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**LA**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	N/A	N/A	X	N/A	X	X	X	X	X	X	N/A	N/A	X

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Key References:

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