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| --- | --- | --- | --- |
| **Criteria Title** | Enzyme Replacement Therapy for GBA gene mutation disorder | | |
| **Criteria Subtitle** | Cerezyme (imiglucerase), Elelyso (taliglucerase alfa), Vpriv (velaglucerase alfa) | | |
| **Approval Level** | GCNSeqNo | | |
| **Products**   |  |  | | --- | --- | | Preferred |  | | Non-Preferred |  | | Brand |  | | Generic |  | | Other |  | | Drug Name | Corresponding Code(s) | Type of Code (GCNSeqNo, HICL, NDC) |
| CEREZYME | 043462 | GCNSeqNo |
| ELELYSO | 069127 | GCNSeqNo |
| VPRIV | 066109 | GCNSeqNo |

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| --- | --- | --- | --- | --- | --- | --- |
| **Sequence Number** | **Question ID** | **Default Next Question ID** | **Question Type** | **Question Text** | **Choice Text** | **Next Question ID** |
| 1 | 0999 |  | Select | Is the patient new to therapy (initial authorization request) or continuing therapy (re-authorization request)? | New Start (initial authorization request) | 1000 |
| Continuation (re-authorization request) | 2000 |
| 2 | 1000 |  | Select | Is this request being prescribed in accordance with Food and Drug Administration (FDA) approved labeling? | Y | 1001 |
| N | 1235 |
| 3 | 1001 |  | Select | Is the patient receiving another enzyme therapy (e.g., Zavesca, Cerdelga)? | Y | 1235 |
| N | 1002 |
| 4 | 1002 |  | Select and Free Text | Has the provider submitted documentation of the patient’s  baseline (and at least annual) hemoglobin, platelet count, spleen volume and liver volume tests/examination, DEXA scan?  If yes, please submit documentation. | Y | END (Pending Manual Review) |
| N | 1235 |
| 5 | 2000 |  | Select and Free Text | Has the provider submitted documentation of clinical response (e.g., decreased liver and spleen volume, increased platelet count, increased hemoglobin concentration)?    If yes, please submit documentation. | Y | END (Pending Manual Review) |
| N | 1235 |
| 6 | 1235 |  | Free Text | Please provide the rationale for the medication being requested. | END (Pending Manual Review) | |

LENGTH OF AUTHORIZATIONS: 365 days

|  |  |
| --- | --- |
| **Last Approved** | 4/10/2023 |
| **Other** |  |