**Respiratory Agents: Cystic Fibrosis**

|  |  |
| --- | --- |
| Criteria 1 | Non-Preferred Products: Bronchitol |
| Criteria 2 | Preferred Products: Kalydeco, Orkambi, Symdeko, Trikafta |

|  |  |  |  |
| --- | --- | --- | --- |
| **Criteria Title** | Respiratory Agents: Cystic Fibrosis | | |
| **Criteria Subtitle** | Bronchitol | | |
| **Approval Level** | GCNSeqNo | | |
| **Products**   |  |  | | --- | --- | | Preferred |  | | Non-Preferred | X | | Brand |  | | Generic |  | | Other |  | | Drug Name | Corresponding Code (s) | Type of Code (GCNSeqNo, HICL, NDC) |
| BRONCHITOL | 072179 | GCNSeqNo |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Sequence Number** | **Question ID** | **Default Next Question ID** | **Question Type** | **Question Text** | **Choice Text** | **Next Question ID** |
| 1 | 0998 |  | Select | Is the patient new to therapy (initial authorization request) or continuing therapy (re-authorization request)? | New Start (initial authorization request) | 0999 |
| Continuation (re-authorization request) | 1234 |
| 2 | 0999 |  | Select | Is this request being prescribed in accordance with Food and Drug Administration (FDA) approved labeling? | Y | 1000 |
| N | 1235 |
| 3 | 1000 |  | Select | Is the medication being prescribed by or in consultation with a pulmonologist or infectious disease specialist? | Y | 1001 |
| N | 1235 |
| 4 | 1001 |  | Select and Free Text | Has the provider submitted documentation of the patient’s genetic mutation? | Y | 1002 |
| N | 1235 |
| 5 | 1002 |  | Select | Is Bronchitol being used as an add-on maintenance therapy? | Y | 1003 |
| N | 1235 |
| 6 | 1003 |  | Select and Free Text | Has the provider submitted documentation of a completed Bronchitol Tolerance Test? | Y | 1004 |
| N | 1235 |
| 7 | 1004 |  | Select and Free Text | Has the patient had an inadequate clinical response of at least 30 days with at least one preferred drug?  If yes, please submit the medication trials and dates. | Y | 1006 |
| N | 1005 |
| 8 | 1005 |  | Select and Free Text | Has the provider submitted documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances)?  If yes, please submit the medication name and reason for inability to use. | Y | 1006 |
| N | 1236 |
| 9 | 1006 |  | Select | Is the request for any of the following:  1) a nonsolid oral dosage formulation  2) a non-preferred extended release formulation  3) a non-preferred brand name that has a preferred generic product | Y | 1007 |
| N | END (Pending Manual Review) |
| 10 | 1007 |  | Select and Free Text | Has the provider submitted documentation of medical necessity for the requested product (i.e. medical reasons for why the patient cannot be changed to a solid oral dosage formulation, inadequate clinical response with a product’s immediate release formulation, or inadequate clinical response or allergy of two or more generic labelers)? | Y | END (Pending Manual Review) |
| N | 1235 |
| 11 | 1234 |  | Select and Free Text | Has the provider submitted documentation of the patient’s clinical response to treatment (adherence to treatment demonstrated by claims history AND one or more of the following: FEV1, weight gain, sweat chloride, pulmonary exacerbations, etc.) and ongoing safety monitoring? | Y | END (Pending Manual Review) |
| N | 1235 |
| 12 | 1235 |  | Free Text | Please provide the rationale for the medication being requested. | END (Pending Manual Review) | |
| 13 | 1236 |  | Free Text | Please explain the reason(s) why the patient is unable to use medications not requiring prior approval. | END (Pending Manual Review) | |

LENGTH OF AUTHORIZATIONS: Initial authorization 90 days, subsequent authorization 365 days.

|  |  |
| --- | --- |
| **Last Approved** | 4/20/2023 |
| **Other** |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Criteria Title** | Respiratory Agents: Cystic Fibrosis | | |
| **Criteria Subtitle** | Preferred Products | | |
| **Approval Level** | GCNSeqNo | | |
| **Products**   |  |  | | --- | --- | | Preferred | X | | Non-Preferred |  | | Brand |  | | Generic |  | | Other |  | | Drug Name | Corresponding Code (s) | Type of Code (GCNSeqNo, HICL, NDC) |
| KALYDECO | 068512 | GCNSeqNo |
| KALYDECO | 073697 | GCNSeqNo |
| KALYDECO | 073698 | GCNSeqNo |
| KALYDECO | 079693 | GCNSeqNo |
| ORKAMBI | 074379 | GCNSeqNo |
| ORKAMBI | 076661 | GCNSeqNo |
| ORKAMBI | 078704 | GCNSeqNo |
| ORKAMBI | 078705 | GCNSeqNo |
| ORKAMBI | 083804 | GCNSeqNo |
| SYMDEKO | 078161 | GCNSeqNo |
| SYMDEKO | 079924 | GCNSeqNo |
| TRIKAFTA | 080343 | GCNSeqNo |
| TRIKAFTA | 082377 | GCNSeqNo |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Sequence Number** | **Question ID** | **Default Next Question ID** | **Question Type** | **Question Text** | **Choice Text** | **Next Question ID** |
| 1 | 0998 |  | Select | Is the patient new to therapy (initial authorization request) or continuing therapy (re-authorization request)? | New Start (initial authorization request) | 0999 |
| Continuation (re-authorization request) | 1234 |
| 2 | 0999 |  | Select | Is this request being prescribed in accordance with Food and Drug Administration (FDA) approved labeling? | Y | 1000 |
| N | 1235 |
| 3 | 1000 |  | Select | Is the medication being prescribed by or in consultation with a pulmonologist or infectious disease specialist? | Y | 1001 |
| N | 1235 |
| 4 | 1001 |  | Select and Free Text | Has the provider submitted documentation of the patient’s genetic mutation? | Y | END (Pending Manual Review) |
| N | 1235 |
| 5 | 1234 |  | Select and Free Text | Has the provider submitted documentation of the patient’s clinical response to treatment (adherence to treatment demonstrated by claims history AND one or more of the following: FEV1, weight gain, sweat chloride, pulmonary exacerbations, etc.) and ongoing safety monitoring? | 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: Initial authorization 90 days, subsequent authorization 365 days.

|  |  |
| --- | --- |
| **Last Approved** | 4/20/2023 |
| **Other** |  |