|  |  |
| --- | --- |
| Criteria 1 | Non-Preferred: Arikayce (NP), Bethkis (NP, QL), Cayston (NP), Kitabis Pak (NP, QL), Tobi Podhaler (NP, QL) |
| Criteria 2 | Tobramycin (P, QL, PA) |

|  |  |  |  |
| --- | --- | --- | --- |
| **Criteria Title** | Infectious Disease Agents: Antibiotics – Inhaled | | |
| **Criteria Subtitle** | Non-Preferred Products | | |
| **Approval Level** | GCNSeqNo | | |
| **Products**   |  |  | | --- | --- | | Preferred |  | | Non-Preferred | X | | Brand |  | | Generic |  | | Other |  | | Drug Name | Corresponding Code(s) | Type of Code (GCNSeqNo, HICL, NDC) |
| ARIKAYCE | 079020 | GCNSeqNo |
| BETHKIS | 064682 | GCNSeqNo |
| CAYSTON | 065913 | GCNSeqNo |
| KITABIS PAK | 073201 | GCNSeqNo |
| TOBI PODHALER | 067462 | GCNSeqNo |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **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 and Free Text | Has the provider submitted documentation of cultures demonstrating that the requested drug is prescribed in alignment with an approved indication?  If yes, please submit documentation. | Y | 1002 |
| N | 1235 |
| 4 | 1002 |  | Select and Free Text | Has the patient had an inadequate clinical response of at least 28 days with at least one preferred drug?  If yes, please submit the medication trials and dates. | Y | 1004 |
| N | 1003 |
| 5 | 1003 |  | 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 | 1004 |
| N | 1236 |
| 6 | 1004 |  | 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 | 1005 |
| N | 1006 |
| 7 | 1005 |  | 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 | 1006 |
| N | 1235 |
| 8 | 1006 |  | Select | What product is being requested? | Arikayce | END (Pending Manual Review) |
| Bethkis | 1007 |
| Cayston | END (Pending Manual Review) |
| Kitabis Pak | 1007 |
| Tobi Podhaler | 1007 |
| Other | 1235 |
| 9 | 1007 |  | Select | Ohio Medicaid covers up to 56 doses in 56 days.  Does this request meet this requirement? | Y | END (Pending Manual Review) |
| N | 1235 |
| 10 | 2000 |  | Select and Free Text | Has the provider submitted documentation of the patient’s clinical response to treatment and ongoing safety monitoring (i.e., culture conversion, symptom improvement)?  If yes, please submit documentation. | Y | 2001 |
| N | 1235 |
| 11 | 2001 |  | Select | What product is being requested? | Arikayce | END (Pending Manual Review) |
| Bethkis | 2002 |
| Cayston | END (Pending Manual Review) |
| Kitabis Pak | 2002 |
| Tobi Podhaler | 2002 |
| Other | 1235 |
| 12 | 2002 |  | Select | Ohio Medicaid covers up to 56 doses in 56 days.  Does this request meet this requirement? | Y | END (Pending Manual Review) |
| N | 1235 |
| 13 | 1235 |  | Free Text | Please provide the rationale for the medication being requested. | END (Pending Manual Review) | |
| 14 | 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 authorizations- 180 days; Subsequent authorizations- 365 days

|  |  |
| --- | --- |
| **Last Approved** | 5/17/2023 |
| **Other** |  |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Criteria Title** | | | Infectious Disease Agents: Antibiotics – Inhaled | | | | | | | |
| **Criteria Subtitle** | | | Preferred Products | | | | | | | |
| **Approval Level** | | | NDC-9 | | | | | | | |
| **Products**   |  |  | | --- | --- | | Preferred | X | | Non-Preferred |  | | Brand |  | | Generic |  | | Other |  | | | | Drug Name | | | Corresponding Code(s) | | Type of Code (GCNSeqNo, HICL, NDC) | | |
| TOBRAMYCIN | | | 064682 | | GCNSeqNo | | |
| TOBRAMYCIN | | | 037042 | | GCNSeqNo | | |
| TOBRAMYCIN | | | 073201 | | GCNSeqNo | | |
| **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 and Free Text | Has the provider submitted documentation of cultures demonstrating that the requested drug is prescribed in alignment with an approved indication?  If yes, please submit documentation. | | Y | | 1002 |
| N | | 1235 |
| 4 | 1002 |  | | Select | Ohio Medicaid covers up to 56 doses in 56 days.  Does this request meet this requirement? | | Y | | END (Pending Manual Review) |
| N | | 1235 |
| 5 | 2000 |  | | Select and Free Text | Has the provider submitted documentation of the patient’s clinical response to treatment and ongoing safety monitoring (i.e., culture conversion, symptom improvement)?  If yes, please submit documentation. | | Y | | 2001 |
| N | | 1235 |
| 6 | 2001 |  | | Select | Ohio Medicaid covers up to 56 doses in 56 days.  Does this request meet this requirement? | | Y | | END (Pending Manual Review) |
| N | | 1235 |
| 7 | 1235 |  | | Free Text | Please provide the rationale for the medication being requested. | | END (Pending Manual Review) | | |

LENGTH OF AUTHORIZATIONS: Initial authorizations- 180 days; Subsequent authorizations- 365 days

|  |  |
| --- | --- |
| **Last Approved** | 5/17/2023 |
| **Other** |  |