**Gastrointestinal Agents: Irritable Bowel Syndrome (IBS) with Diarrhea**

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| Criteria 1 | NP- Alosetron, Viberzi |
| Criteria 2 | ST- Xifaxan |

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| **Criteria Title** | Gastrointestinal Agents: Irritable Bowel Syndrome (IBS) with Diarrhea | | |
| **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) |
| ALOSETRON | 044634 | GCNSeqNo |
| ALOSETRON | 053708 | GCNSeqNo |
| VIBERZI | 074654 | GCNSeqNo |
| VIBERZI | 074655 | GCNSeqNo |

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| **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 and Free Text | Has the patient had an inadequate clinical response of at least 30 days with at least two preferred drugs?  The preferred alternatives may include the following: Diphenoxylate/Atropine, Loperamide, Xifaxan.  If yes, please submit the medication trials and dates. | Y | 1002 |
| N | 1001 |
| 4 | 1001 |  | 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 | 1002 |
| N | 1236 |
| 5 | 1002 |  | 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 | 1003 |
| N | END (Approve x 365 Days) |
| 6 | 1003 |  | 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 (Approve x 365 days) |
| N | 1235 |
| 7 | 1234 |  | Select and Free Text | Has the provider submitted documentation of the patient’s clinical response to treatment and ongoing safety monitoring? | Y | END (Approve x 365 days) |
| N | 1235 |
| 8 | 1235 |  | Free Text | Please provide the rationale for the medication being requested. | END (Pending Manual Review) | |
| 9 | 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: 365 Days

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

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| **Criteria Title** | Gastrointestinal Agents: Hepatic Encephalopathy, Irritable Bowel Syndrome (IBS) with Diarrhea, Unspecified GI | | |
| **Criteria Subtitle** | Xifaxan | | |
| **Approval Level** | GCNSeqNo | | |
| **Products**   |  |  | | --- | --- | | Preferred | X | | Non-Preferred |  | | Brand | X | | Generic |  | | Other |  | | Drug Name | Corresponding Code (s) | Type of Code (GCNSeqNo, HICL, NDC) |
| XIFAXAN | 041880 | GCNSeqNo |
| XIFAXAN | 066295 | 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 | What is the patient’s diagnosis? | Hepatic Encephalopathy | 1000 |
| Irritable Bowel Syndrome (IBS) with Diarrhea | 2000 |
| Unspecified Gastrointestinal | 3000 |
| Other | 1235 |
| 2 | 1000 |  | Select | Is the patient new to therapy (initial authorization request) or continuing therapy (re-authorization request)? | New Start (initial authorization request) | 1001 |
| Continuation (re-authorization request) | 1233 |
| 3 | 1001 |  | Select | Is this request being prescribed in accordance with Food and Drug Administration (FDA) approved labeling? | Y | 1002 |
| N | 1235 |
| 4 | 1002 |  | Select and Free Text | Has the patient had an inadequate clinical response of at least 14 days with at least one preferred drug?  The preferred alternatives may include the following: Lactulose.  If yes, please submit the medication trials and dates. | Y | 1003 |
| N | 1004 |
| 5 | 1003 |  | Select and Free Text | Has the patient had an inadequate clinical response of at least 14 days to lactulose?  If yes, please submit the medication trials and dates. | Y | END (Approve x 365 days) |
| N | 1004 |
| 6 | 1004 |  | 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 | END (Approve x 365 days) |
| N | 1236 |
| 7 | 2000 |  | Select | Is the patient new to therapy (initial authorization request) or continuing therapy (re-authorization request)? | New Start (initial authorization request | 2001 |
| Continuation (re-authorization request) | 1233 |
| 8 | 2001 |  | Select | Is this request being prescribed in accordance with Food and Drug Administration (FDA) approved labeling? | Y | 2002 |
| N | 1235 |
| 9 | 2002 |  | Select and Free Text | Has the patient had an inadequate clinical response of at least 30 days with at least one preferred drug?  The preferred alternatives may include the following: Diphenoxylate/Atropine, Loperamide.  If yes, please submit the medication trials and dates. | Y | END (Approve x 365 days) |
| N | 2003 |
| 10 | 2003 |  | 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 | END (Approve x 365 days) |
| N | 1236 |
| 11 | 3000 |  | Select | Is the patient new to therapy (initial authorization request) or continuing therapy (re-authorization request)? | New Start (initial authorization request | 3001 |
| Continuation (re-authorization request) | 1234 |
| 12 | 3001 |  | Select | Is this request being prescribed in accordance with Food and Drug Administration (FDA) approved labeling? | Y | 3002 |
| N | 1235 |
| 13 | 3002 |  | Select and Free Text | Has the patient had an inadequate clinical response of at least 14 days with at least two preferred drugs?  If yes, please submit the medication trials and dates. | Y | END (Pending Manual Review) |
| N | 3003 |
| 14 | 3003 |  | 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 | END (Pending Manual Review) |
| N | 1236 |
| 15 | 1233 |  | Select and Free Text | Has the provider submitted documentation of the patient’s clinical response to treatment and ongoing safety monitoring? | Y | END (Approve x 365 days) |
| N | 1235 |
| 16 | 1234 |  | Select and Free Text | Has the provider submitted documentation of the patient’s clinical response to treatment and ongoing safety monitoring (i.e., decreased frequency of specialized nutrition support or improvement in symptoms)? | Y | END (Pending Manual Review) |
| N | 1235 |
| 17 | 1235 |  | Free Text | Please provide the rationale for the medication being requested. | END (Pending Manual Review) | |
| 18 | 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: 365 Days

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