**Respiratory Agents: Monoclonal Antibodies-Anti-IL/Anti-IgE**

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| Criteria 1 | Preferred Agents – Fasenra (PA), Xolair (PA) |
| Criteria 2 | Preferred Agents – Dupixent (PA) |
| Criteria 3 | Non-Preferred Agents – Nucala, Tezspire |

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| **Criteria Title** | Respiratory Agents: Monoclonal Antibodies-Anti-IL/Anti-IgE | | |
| **Criteria Subtitle** | Fasenra, Xolair | | |
| **Approval Level** | GCNSeqNo | | |
| **Products**   |  |  | | --- | --- | | Preferred | X | | Non-Preferred |  | | Brand |  | | Generic |  | | Other |  | | Drug Name | Corresponding Code(s) | Type of Code (GCNSeqNo, HICL, NDC) |
| FASENRA | 077921 | GCNSeqNo |
| FASENRA | 080268 | GCNSeqNo |
| XOLAIR | 052758 | GCNSeqNo |
| XOLAIR | 067907 | GCNSeqNo |
| XOLAIR | 067908 | 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 | Is the medication being prescribed by or in consultation with an applicable specialist (i.e., allergist/immunologist, pulmonologist, or otolaryngologist)? | Y | 1001 |
| N | 1235 |
| 4 | 1001 |  | Select | What is the patient’s diagnosis? | Asthma | 2000 |
| Chronic Rhinosinusitis with Nasal Polyposis | 3000 |
| Chronic Urticaria | 4000 |
| Other | 1235 |
| 5 | 2000 |  | Select | What is the patient’s age? | 6-11 years old | 2001 |
| 12 years and older | 2002 |
| 6 | 2001 |  | Select and Free Text | Has the patient had uncontrolled asthma symptoms and/or exacerbations despite at least 30 days with a medium dose preferred ICS/LABA inhaler?  If yes, please submit the medication trials and dates. | Y | END (Pending Manual Review) |
| N | 1233 |
| 7 | 2002 |  | Select and Free Text | Has the patient had uncontrolled asthma symptoms and/or exacerbations despite at least 30 days with a medium dose preferred ICS/LABA inhaler with tiotropium or high dose ICS/LABA inhaler?  If yes, please submit the medication trials and dates. | Y | END (Pending Manual Review) |
| N | 1233 |
| 8 | 3000 |  | Select and Free Text | Has the patient had an inadequate clinical response of at least 30 days to at least one oral corticosteroid AND one nasal corticosteroid spray?    If yes, please submit the medication trials and dates. | Y | END (Pending Manual Review) |
| N | 1233 |
| 9 | 4000 |  | Select and Free Text | Has the patient had an inadequate clinical response to at least 14 days with at least two different antihistamines?  If yes, please submit the medication trials and dates. | Y | END (Pending Manual Review) |
| N | 1233 |
| 10 | 1233 |  | 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 |
| 11 | 1234 |  | Select and Free Text | Has the provider submitted documentation of the patient’s clinical response to treatment and ongoing safety monitoring (i.e., Pulmonary Function Test (PFT) improvement, reduced affected Body Surface Area (BSA))? | 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: 180 days; Subsequent: 365 days

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| **Last Approved** | 4/13/2023 |
| **Other** |  |

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| **Criteria Title** | Immunomodulator Agents: Systemic Inflammatory Disease and Respiratory Agents: Monoclonal Antibodies-Anti-IL/Anti-IgE | | |
| **Criteria Subtitle** | Dupixent | | |
| **Approval Level** | GCNSeqNo | | |
| **Products**   |  |  | | --- | --- | | Preferred | X | | Non-Preferred |  | | Brand |  | | Generic |  | | Other |  | | Drug Name | Corresponding Code (s) | Type of Code (GCNSeqNo, HICL, NDC) |
| DUPIXENT | 077263 | GCNSeqNo |
| DUPIXENT | 079179 | GCNSeqNo |
| DUPIXENT | 081231 | GCNSeqNo |
| DUPIXENT | 081615 | GCNSeqNo |
| DUPIXENT | 082769 | 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? | Asthma | 1000 |
| Chronic Rhinosinusitis with Nasal Polyposis | 2000 |
| Chronic Urticaria | 1235 |
| Alopecia Areata | 1235 |
| Atopic dermatitis | 3000 |
| Plaque psoriasis | 1235 |
| Ulcerative colitis | 1235 |
| 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 | Is the medication being prescribed by or in consultation with an applicable specialist (i.e., allergist/ immunologist, pulmonologist, or otolaryngologist)? | Y | 1003 |
| N | 1235 |
| 5 | 1003 |  | Select | What is the patient’s age? | 6-11 years old | 1004 |
| 12 years and older | 1005 |
| 6 | 1004 |  | Select and Free Text | Has the patient had uncontrolled asthma symptoms and/or exacerbations despite at least 30 days with a medium dose preferred ICS/LABA inhaler?  If yes, please submit the medication trials and dates. | Y | END (Pending Manual Review) |
| N | 1006 |
| 7 | 1005 |  | Select and Free Text | Has the patient had uncontrolled asthma symptoms and/or exacerbations despite at least 30 days with a medium dose preferred ICS/LABA inhaler with tiotropium or high dose ICS/LABA inhaler?  If yes, please submit the medication trials and dates. | Y | END (Pending Manual Review) |
| N | 1006 |
| 8 | 1006 |  | 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 |
| 9 | 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 |
| 10 | 2001 |  | Select | Is this request being prescribed in accordance with Food and Drug Administration (FDA) approved labeling? | Y | 2002 |
| N | 1235 |
| 11 | 2002 |  | Select | Is the medication being prescribed by or in consultation with an applicable specialist (i.e., allergist/ immunologist, pulmonologist, or otolaryngologist)? | Y | 2003 |
| N | 1235 |
| 12 | 2003 |  | Select and Free Text | Has the patient had an inadequate clinical response of at least 30 days to at least one oral corticosteroid AND one nasal corticosteroid spray?  If yes, please submit the medication trials and dates. | Y | END (Pending Manual Review) |
| N | 2004 |
| 13 | 2004 |  | 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 |
| 14 | 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 |
| 15 | 3001 |  | Select | Is this request being prescribed in accordance with Food and Drug Administration (FDA) approved labeling? | Y | 3002 |
| N | 1235 |
| 16 | 3002 |  | Select and Free Text | Authorization of dosing regimens (loading/maintenance) will be based upon diagnosis.    Has the provider submitted documentation of the requested loading and maintenance dosing, if applicable? | Y | 3003 |
| N | 1235 |
| 17 | 3003 |  | Select | Does the patient have a current, active infection? | Y | 1235 |
| N | 3004 |
| 18 | 3004 |  | Select and Free Text | Has the provider submitted evidence of a negative tuberculosis (TB) test prior to initiation of biologic therapy, if required by labeling? | Y | 3005 |
| N | 1235 |
| 19 | 3005 |  | Select and Free Text | Has the patient had an inadequate clinical response of at least 90 days with at least two applicable first-line drugs indicated for diagnosis?  If yes, please provide documentation of the trialed drugs, dosages, dates, and durations. | Y | 3007 |
| N | 3006 |
| 20 | 3006 |  | 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 | 3007 |
| N | 1236 |
| 21 | 3007 |  | Select and Free Text | Does the patient have at least 10% body surface area (BSA) involvement with two of the following: topical corticosteroids or topical calcineurin inhibitors [e.g., Elidel]?  If yes, please submit the medication trials and dates. | Y | END (Pending Manual Review) |
| N | 3008 |
| 22 | 3008 |  | Select | Is the patient’s atopic dermatitis severe and involves greater than 25% BSA? | Y | END (Pending Manual Review) |
| N | 1236 |
| 23 | 1233 |  | Select and Free Text | Has the provider submitted documentation of the patient’s clinical response to treatment and ongoing safety monitoring (i.e., Pulmonary Function Test (PFT) improvement, reduced affected Body Surface Area (BSA))? | Y | END (Pending Manual Review) |
| N | 1235 |
| 24 | 1234 |  | Select and Free Text | Has the provider submitted documentation of the patient’s clinical response to treatment and ongoing safety monitoring? | Y | END (Pending Manual Review) |
| N | 1235 |
| 25 | 1235 |  | Free Text | Please provide the rationale for the medication being requested. | END (Pending Manual Review) | |
| 26 | 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:

Respiratory Agents: Monoclonal Antibodies-Anti-IL/Anti-IgE - Initial: 180 days; Subsequent: 365 days

Immunomodulator Agents: Systemic Inflammatory Disease- Initial: 90 days; Subsequent: 365 days

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| **Last Approved** | 4/13/2023 |
| **Other** |  |

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| **Criteria Title** | Respiratory Agents: Monoclonal Antibodies-Anti-IL/Anti-IgE | | |
| **Criteria Subtitle** | Nucala, Tezspire | | |
| **Approval Level** | GCNSeqNo | | |
| **Products**   |  |  | | --- | --- | | Preferred |  | | Non-Preferred | X | | Brand |  | | Generic |  | | Other |  | | Drug Name | Corresponding Code (s) | Type of Code (GCNSeqNo, HICL, NDC) |
| NUCALA | 075111 | GCNSeqNo |
| NUCALA | 079828 | GCNSeqNo |
| NUCALA | 079829 | GCNSeqNo |
| NUCALA | 083454 | GCNSeqNo |
| TEZSPIRE | 082944 | 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 | Is the medication being prescribed by or in consultation with an applicable specialist (i.e., allergist/immunologist, pulmonologist, or otolaryngologist)? | Y | 1001 |
| N | 1235 |
| 4 | 1001 |  | Select | What is the patient’s diagnosis? | Asthma | 2000 |
| Chronic Rhinosinusitis with Nasal Polyposis | 3000 |
| Chronic Urticaria | 4000 |
| Other | 1235 |
| 5 | 2000 |  | Select | What is the patient’s age? | 6-11 years old | 2001 |
| 12 years and older | 2002 |
| 6 | 2001 |  | Select and Free Text | Has the patient had uncontrolled asthma symptoms and/or exacerbations despite at least 30 days with a medium dose preferred ICS/LABA inhaler?  If yes, please submit the medication trials and dates. | Y | 1230 |
| N | 1236 |
| 7 | 2002 |  | Select and Free Text | Has the patient had uncontrolled asthma symptoms and/or exacerbations despite at least 30 days with a medium dose preferred ICS/LABA inhaler with tiotropium or high dose ICS/LABA inhaler?  If yes, please submit the medication trials and dates. | Y | 1230 |
| N | 1236 |
| 8 | 3000 |  | Select and Free Text | Has the patient had an inadequate clinical response of at least 30 days to at least one oral corticosteroid AND one nasal corticosteroid spray?  If yes, please submit the medication trials and dates. | Y | 1230 |
| N | 1236 |
| 9 | 4000 |  | Select and Free Text | Has the patient had an inadequate clinical response to at least 14 days with at least two different antihistamines?    If yes, please submit the medication trials and dates. | Y | 1230 |
| N | 1236 |
| 10 | 1230 |  | Select and Free Text | Has the patient had an inadequate clinical response of at least 90 days with at least one preferred drug?  If yes, please submit the medication trials and dates. | Y | 1232 |
| N | 1231 |
| 11 | 1231 |  | 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 | 1232 |
| N | 1236 |
| 12 | 1232 |  | 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 | 1233 |
| N | END (Pending Manual Review) |
| 13 | 1233 |  | 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 |
| 14 | 1234 |  | Select and Free Text | Has the provider submitted documentation of the patient’s clinical response to treatment and ongoing safety monitoring (i.e., Pulmonary Function Test (PFT) improvement, reduced affected Body Surface Area (BSA))? | Y | END (Pending Manual Review) |
| N | 1235 |
| 15 | 1235 |  | Free Text | Please provide the rationale for the medication being requested. | END (Pending Manual Review) | |
| 16 | 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: 180 days; Subsequent: 365 days

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| **Last Approved** | 4/13/2023 |
| **Other** |  |