**Dermatological Oral Acne Products**

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| Criteria 1 | P agents with PA (Accutane, Amnesteem, Claravis, Isotretinoin, Myorisan, Zenatane) |
| Criteria 2 | NP agents (Absorica, Absorica LD) |

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| **Criteria Title** | Dermatologic Agents: Oral Acne Products | | |
| **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) |
| ACCUTANE | 036045 | GCNSeqNo |
| ACCUTANE | 036046 | GCNSeqNo |
| ACCUTANE | 036047 | GCNSeqNo |
| ACCUTANE | 053055 | GCNSeqNo |
| AMNESTEEM | 036045 | GCNSeqNo |
| AMNESTEEM | 036046 | GCNSeqNo |
| AMNESTEEM | 036047 | GCNSeqNo |
| CLARAVIS | 036045 | GCNSeqNo |
| CLARAVIS | 036046 | GCNSeqNo |
| CLARAVIS | 036047 | GCNSeqNo |
| CLARAVIS | 053055 | GCNSeqNo |
| ISOTRETINOIN | 036045 | GCNSeqNo |
| ISOTRETINOIN | 036046 | GCNSeqNo |
| ISOTRETINOIN | 036047 | GCNSeqNo |
| ISOTRETINOIN | 053055 | GCNSeqNo |
| ISOTRETINOIN | 072730 | GCNSeqNo |
| ISOTRETINOIN | 072731 | GCNSeqNo |
| MYORISAN | 036045 | GCNSeqNo |
| MYORISAN | 036046 | GCNSeqNo |
| MYORISAN | 063047 | GCNSeqNo |
| MYORISAN | 053055 | GCNSeqNo |
| ZENATANE | 036045 | GCNSeqNo |
| ZENATANE | 036046 | GCNSeqNo |
| ZENATANE | 036047 | GCNSeqNo |
| ZENATANE | 053055 | GCNSeqNo |

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| **Sequence Number** | **Question ID** | **Default Next Question ID** | **Question Type** | **Question Text** | **Choice Text** | **Next Question ID** |
| 1 | 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 |
| 2 | 1001 |  | Select | Is this request being prescribed in accordance with Food and Drug Administration (FDA) approved labeling? | Y | 1002 |
| N | 1235 |
| 3 | 1002 |  | Select | Is the patient registered and does the patient meet all of the requirements of the iPLEDGE program? | Y | 1003 |
| N | 1235 |
| 4 | 1003 |  | Select and Free Text | Has the patient had an inadequate clinical response of at least 90 days with at least one preferred topical for acne?  If yes, please submit the medication trials and dates. | Y | 1004 |
| N | 1235 |
| 5 | 1004 |  | Select and Free Text | Has the patient had an inadequate clinical response of at least 90 days with at least one preferred oral antibiotic for acne?  If yes, please submit the medication trials and dates. | Y | 1005 |
| N | 1235 |
| 6 | 1005 |  | Select | Has the patient been absent oral tretinoin in the past 56 days? | Y | END (Pending Manual Review) |
| N | 1235 |
| 7 | 1233 |  | Select and Free Text | Has the provider submitted documentation of the patient’s clinical response to treatment and ongoing safety monitoring? | Y | 1234 |
| N | 1235 |
| 8 | 1234 |  | Select | Has the patient been absent oral tretinoin in the past 56 days? | Y | END (Pending Manual Review) |
| N | 1235 |
| 9 | 1235 |  | Free Text | Please provide the rationale for the medication being requested. | END (Pending Manual Review) | |

LENGTH OF AUTHORIZATIONS: 150 days

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

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| **Criteria Title** | Dermatologic Agents: Oral Acne Products | | |
| **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) |
| ABSORBICA | 036045 | GCNSeqNo |
| ABSORBICA | 036046 | GCNSeqNo |
| ABSORBICA | 036047 | GCNSeqNo |
| ABSORBICA | 053055 | GCNSeqNo |
| ABSORBICA | 072730 | GCNSeqNo |
| ABSORBICA | 072731 | GCNSeqNo |
| ABSORBICA LD | 080449 | GCNSeqNo |
| ABSORBICA LD | 080450 | GCNSeqNo |
| ABSORBICA LD | 080452 | GCNSeqNo |
| ABSORBICA LD | 080454 | GCNSeqNo |

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| **Sequence Number** | **Question ID** | **Default Next Question ID** | **Question Type** | **Question Text** | **Choice Text** | **Next Question ID** |
| 1 | 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 |
| 2 | 1001 |  | Select | Is this request being prescribed in accordance with Food and Drug Administration (FDA) approved labeling? | Y | 1002 |
| N | 1235 |
| 3 | 1002 |  | Select | Is the patient registered and does the patient meet all of the requirements of the iPLEDGE program? | Y | 1003 |
| N | 1235 |
| 4 | 1003 |  | Select and Free Text | Has the patient had an inadequate clinical response of at least 90 days with at least one preferred topical for acne?  If yes, please submit the medication trials and dates. | Y | 1004 |
| N | 1235 |
| 5 | 1004 |  | Select and Free Text | Has the patient had an inadequate clinical response of at least 90 days with at least one preferred oral antibiotic for acne?  If yes, please submit the medication trials and dates. | Y | 1005 |
| N | 1235 |
| 6 | 1005 |  | Select and Free Text | Has the patient had an inadequate clinical response of at least 90 days with at least two preferred drugs?  If yes, please submit the medication trials and dates. | Y | 1007 |
| N | 1006 |
| 7 | 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 | 1007 |
| N | 1236 |
| 8 | 1007 |  | Select | Has the patient been absent oral tretinoin in the past 56 days? | Y | 1008 |
| N | 1235 |
| 9 | 1008 |  | 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 | 1009 |
| N | END (Pending Manual Review) |
| 10 | 1009 |  | 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 | 1233 |  | Select and Free Text | Has the provider submitted documentation of the patient’s clinical response to treatment and ongoing safety monitoring? | Y | 1234 |
| N | 1235 |
| 12 | 1234 |  | Select | Has the patient been absent oral tretinoin in the past 56 days? | 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: 150 days

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