**Endocrine Agents: Osteoporosis – Bone Ossification Enhancers**

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| Criteria 1 | NP - Alendronate Susp, Fosamax Plus D, Risedronate |
| Criteria 2 | Forteo |
| Criteria 3 | Tymlos |

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| **Criteria Title** | Endocrine Agents: Osteoporosis – Bone Ossification Enhancers | | |
| **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) |
| ALENDRONATE SUSP | 053574 | GCNSeqNo |
| FOSAMAX PLUS D | 058947 | GCNSeqNo |
| FOSAMAX PLUS D | 062663 | GCNSeqNo |
| RISEDRONATE | 040294 | GCNSeqNo |
| RISEDRONATE | 045102 | GCNSeqNo |
| RISEDRONATE | 050364 | GCNSeqNo |
| RISEDRONATE | 063925 | GCNSeqNo |
| RISEDRONATE | 066815 | 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 365 days with at least one preferred drug within the same class?  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 (Pending Manual Review) |
| 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 (Pending Manual Review) |
| 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 (Pending Manual Review) |
| 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** | Endocrine Agents: Osteoporosis – Bone Ossification Enhancers | | |
| **Criteria Subtitle** | Forteo | | |
| **Approval Level** | GCNSeqNo | | |
| **Products**   |  |  | | --- | --- | | Preferred | X | | Non-Preferred |  | | Brand |  | | Generic |  | | Other |  | | Drug Name | Corresponding Code (s) | Type of Code (GCNSeqNo, HICL, NDC) |
| FORTEO | 064481 | 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) | 1233 |
| 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 365 days with one bisphosphonate?  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 | Will the patient’s total lifetime duration of therapy between any parathyroid analog exceed 730 days (2 years)? | Y | 1235 |
| N | END (Pending Manual Review) |
| 6 | 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 |
| 7 | 1234 |  | Select | Will the patient’s total lifetime duration of therapy between any parathyroid analog exceed 730 days (2 years)? | Y | 1235 |
| N | END (Pending Manual Review) |
| 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** | Endocrine Agents: Osteoporosis – Bone Ossification Enhancers | | |
| **Criteria Subtitle** | Tymlos | | |
| **Approval Level** | GCNSeqNo | | |
| **Products**   |  |  | | --- | --- | | Preferred |  | | Non-Preferred | X | | Brand |  | | Generic |  | | Other |  | | Drug Name | Corresponding Code (s) | Type of Code (GCNSeqNo, HICL, NDC) |
| TYMLOS | 077351 | GCNSeqNo |

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| **Sequence Number** | **Question ID** | **Default Next Question ID** | **Question Type** | **Question Text** | **Choice Text** | **Next Question ID** |
| 1 | 0997 |  | Select | Is the patient new to therapy (initial authorization request) or continuing therapy (re-authorization request)? | New Start (initial authorization request) | 0998 |
| Continuation (re-authorization request) | 1233 |
| 2 | 0998 |  | Select | Is this request being prescribed in accordance with Food and Drug Administration (FDA) approved labeling? | Y | 0999 |
| N | 1235 |
| 3 | 0999 |  | Select and Free Text | Has the patient had an inadequate clinical response of at least 365 days with at least one preferred drug within the same class?  If yes, please submit the medication trials and dates. | Y | 1000 |
| N | 1001 |
| 4 | 1000 |  | Select and Free Text | Has the patient had an inadequate clinical response of at least 365 days with one bisphosphonate?  If yes, please submit the medication trials and dates. | Y | 1002 |
| N | 1001 |
| 5 | 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 |
| 6 | 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 | 1004 |
| 7 | 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 | 1004 |
| N | 1235 |
| 8 | 1004 |  | Select | Will the patient’s total lifetime duration of therapy between any parathyroid analog exceed 730 days (2 years)? | Y | 1235 |
| N | END (Pending Manual Review) |
| 9 | 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 |
| 10 | 1234 |  | Select | Will the patient’s total lifetime duration of therapy between any parathyroid analog exceed 730 days (2 years)? | Y | 1235 |
| N | END (Pending Manual Review) |
| 11 | 1235 |  | Free Text | Please provide the rationale for the medication being requested. | END (Pending Manual Review) | |
| 12 | 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** |  |