Pharmacy Policy

Spinal Muscular Atrophy (SMA) Agents – Unified Formulary

Policy Number: 9.331
Version Number: 1
Version Effective Date: 1/1/2021

Product Applicability	☐ **All Plan+ Products**
Well Sense Health Plan	**Boston Medical Center HealthNet Plan**
☐ New Hampshire Medicaid	☒ MassHealth- MCO ☒ MassHealth- ACO ☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct ☐ Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Reference Table:

Drugs that require PA	No PA
Zolgensma® (onasemnogene abeparvovec-xioi)CO PD ^	

CO Carve Out. This agent is listed on the Acute Hospital Carve-Out Drugs List and is subject to additional monitoring and billing requirements.
PD Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Please note, for SMA agents, a trial with a preferred agent is not required prior to approval of a non-preferred agent.
^This agent is available through the health care professional who administers the drug. MassHealth does not pay for this drug to be dispensed through a retail pharmacy.

Procedure:

Approval Diagnosis:	Spinal Muscular Atrophy (SMA) –Zolgensma®
Approval Criteria: **Zolgensma®** (onasemnogene abeparvovec-xioi) CO ^	• **NOTE**: All prior authorization requests should be summarized and forwarded to the Clinical Reviewer of the day. Cases will be reviewed with DUR Management prior to issuing a decision. If clinical review/supervisor is not available, regardless of compliance, please forward to clinical review for follow-up.

+ *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

	Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis (Type 1, 2 or 3 SMA)* 2. Member is <2 years of age 3. Prescriber is a neuromuscular specialist 4. Copy of genetic test confirming diagnosis of bi-allelic mutation in the SMA1 gene (e.g. SMN1 homozygous gene deletion or mutation or compound heterozygous mutation) 5. Copy of genetic test confirming the member has two or three copies of the SMN2 gene 6. Copy of baseline AAV9 antibody test confirming titers < 1:50 7. Member does not have evidence of complete paralysis of limbs 8. Member does not have evidence of permanent ventilator dependence at the time Zolgensma® is to be administered, defined as **ANY** of the following:† o Member has an endotracheal tube o Member has a tracheotomy tube o Member had at least 14 days of continuous respiratory assistance for at least 16 hours per day Notes: • **Please forward any requests for individuals with Type 4 SMA to the Clinical Reviewer of the day.* • *†Refer to Appendix: Zolgensma Ventilator Dependence for additional information on how to review.* • *Member is limited to a maximum of one treatment course with this regimen* • *Due to the ^ (caret) designation, requests can only be processed in MMIS for office billing. NO PHARMACY/POPS APPROVALS ALLOWED.* • *This agent is listed on the Acute Hospital Carve-Out Drugs List and is subject to additional monitoring and billing requirements.* • *Due to the nature of this disease, if a request is denied, the prescriber should be contacted and informed of the additional clinical documentation that is required on resubmission*
Denial Criteria:	Cases that do not meet the approval criteria will be denied.
	If a request is denied and the prescriber has additional clinical documentation, a **new** prior authorization request must be submitted.
Duration/Quantity of Authorization:	Initial approval may be granted for 6 months.
Recertification Criteria:	**Zolgensma®:** Recertification requests for Zolgensma will be evaluated based on the member having received the medication in the past or not. • Member has never received Zolgensma® → review using initial approval criteria • Member has received Zolgensma® in the past → forward to clinical review

Appendix:

Stability

Zolgensma® (onasemnogene abeparvovec-xioi) is a one-time dose, thus stability does not apply.

Additional Information

† *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

Classifications of SMA[1]

SMA Type	Age of Onset	Highest Function	Natural Age of Death
Type 0 (prenatal)	Pre-natal/fetal	Never sits	<6 months (usually <1 month)
Type 1 (infantile) Werdnig-Hoffman disease	0 to 6 months	Never sits	<2 years
Type 2 (intermediate)	3 to 15 months	Never stands	variable (>2 years; up to 66% alive at age 25)
Type 3 (juvenile) Kugelberg-Welander disease	>18 months	Stands and walks	Normal
Type 4 (late-onset, adult)	Not well defined (second or third decade)	Walks during adult years	Normal

Requests for Type 4 SMA

Zolgensma® (onasemnogene abeparvovec-xioi)
Zolgensma® (onasemnogene abeparvovec-xioi) is FDA-approved for children less than two years of age with a diagnosis of SMA. While the FDA-approval does not specifically restrict use based on subtype, SMA type 4 is typically considered late-onset or adult-onset SMA. Members less than two years of age should not be diagnosed with SMA type 4. Outreach to the prescriber should occur to ensure the appropriate diagnosis and to discuss any other relevant information.

Zolgensma® Ventilator Dependence

Evidence supporting the efficacy of Zolgensma® (onasemnogene abeparvovec-xioi) in patients with permanent ventilator dependence is limited. MassHealth, in collaboration with the manufacturer, has determined patients with permanent ventilator dependence would not be candidates for Zolgensma® (onasemnogene abeparvovec-xioi). Permanent ventilator dependence has been defined based on exclusion criteria and outcome measures of clinical trials.

Use of invasive ventilatory support (endotracheal tube, tracheotomy tube) or non-invasive ventilatory support (e.g., BiPAP) continuously for at least 14 days at ≥16 hours/day would generally be considered permanent ventilator dependence and a reason to deny.

Although current approval criteria require that members are not dependent on permanent ventilation at the time Zolgensma® will be administered, generally, the members respiratory dependence should be evaluated based on their status at the time of prior authorization review. Additional information may be required to ensure the member will not require continued use of permanent ventilatory support. Examples of situations where current use of ventilatory support for ≥16 hours/day may not be required chronically include an acute reversible illness or perioperative ventilation.

Case-by-Case Evaluation
CR will outreach to the prescriber's office if needed to collect additional information.

- The member is currently dependent on permanent ventilation (invasive or non-invasive), but will not be at the time of Zolgensma® administration.
- The member is currently utilizing invasive ventilation for small periods of time (e.g., tracheotomy tube used only for nighttime ventilatory support).
- The member is currently utilizing non-invasive ventilatory support for ≥16 hours/day but has utilized it for <14 days.

Motor Function Tests/Assessments

All members treated with SMA agents should be monitored for changes in functional status. The tests/assessments below are commonly utilized in the monitoring of patients with SMA (other functional assessments may be used). Tests are individualized based on patient-specific factors such as age and current functional status. Generally, the same assessments should be used over time to; however, different tests may be stopped or added based on changes in patient-specific factors.

Test Name	Description and Scoring
Hammersmith Infant Neurological Examination (HINE)	• Functional Motor Scale • Target population: 2 months to 2 years of age • Three sections (37 items total) 1. Neurologic signs (26 items) ▪ Cranial nerve function, Posture, Movements, Tone, Reflexes 2. Motor milestones (eight items) ▪ Head Control, Sitting, Voluntary grasp, Ability to kick in supine, Rolling, Crawling, Standing, Walking 3. Behaviors (three items) ▪ Conscious state, emotional state, social orientation • Scoring – section 1 (neurologic signs) only o Each item scored from 0 to 3 (0 = more impairment) o Score range: 0 to 78
Hammersmith Functional Motor Scale (HFMS) and **Hammersmith Functional Motor Scale – Expanded (HFMSE)**	• Functional Motor Scale focused on children with SMA o Expanded (HFMSE) scale developed to evaluate motor function in patients with later-onset (types II and III) SMA • Targeted population: ≥ 2 years old (≥ 30 months of age may be preferred) o Below 30 months of age, there was wide variability in performance of control subjects; however, at age 30 months, all controls were able to complete the assessment with score ≥ 39 (on the HFMS). • Contains a detailed manual on evaluations for consistency and scoring for both ambulatory and non-ambulatory individuals • HFMS contains 20 items • HFMSE contains 13 additional items (33 total items) • Motor functions tested include: sitting, rolling, transitions/crawling, standing/stepping, transitions/kneeling, squat/jump, and stairs • Scoring o Each item scored from 0 to 2 (0=unable to perform, 2=performs without modification, adaptation or compensation) o HFMS range: 0 to 40 o HFMSE range: 0 to 66 (0 to 40 + 0 to 26)

Test Name	Description and Scoring
Revised Hammersmith Scale (RHS) for SMA	• Functional rating scale to assess physical abilities in weak SMA type 2 through to strong ambulant SMA type 3 patients (ambulation defined for this scale as ≥10 meters) • Target population: SMA types II and III (age ~≥1 year) • 36 items total o Assessments include, but not limited to: sitting, sitting to lying, lifts head from supine, four-point kneeling/crawling, standing, walking, squat down and up, high kneeling, stand on one leg o Also includes two timed tests (10 meter run/walk, rise from floor) • Also includes World Health Organization (WHO) motor milestones (see below for reference) • Scoring: o 33 of 36 items scored from 0 to 2 (0=least level of ability, 2=highest level of ability) o 3 o 36 items scored from 0 to 1 (0=unable to achieve, 1=able to achieve) o Range: 0 to 69
World Health Organization (WHO) motor milestones	• The world health organization has developed performance criteria for six gross motor milestones o Sitting without support, hands-and-knees crawling, standing with assistance, walking with assistance, standing alone, walking alone • Each milestone has specific definitions that must be followed • Example: Walking alone o Child takes at least five steps independently in upright position with the back straight. One leg moves forward while the other supports most of the body weight. There is no contact with a person or object. • Scoring: o Each milestone is considered "achieved" or "not achieved" o Includes the exact date milestone was achieved based on parent's record form
Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND)	• Motor skill assessment used to evaluate patients with SMA type I (infantile-onset) • Targeted population: Infants and children ~4 months to >4 years of age • Contains 16 items to assess motor function o Areas of assessment include: spontaneous movement (upper extremity), spontaneous movement (lower extremity), hand grip, head in midline with visual stimulation, hip adductors, rolling: elicited from legs, rolling: elicited from arms, shoulder and elbow flexion and horizontal abduction, shoulder and elbow flexion, knee extension, hip flexion and foot dorsiflexion, head control, elbow flexion, neck flexion, head/neck extension, spinal incurvation • Scoring o Each item scored from 0 to 4 (0=no response, 4=complete response) o Range: 0 to 64 • A CHOP-INTEND score >40 is rarely observed for untreated, symptomatic individuals with infantile-onset (Type I) SMA who have 2 SMN2 gene copies
Motor Function Measure Scale-32 item (MFM-32) and **Motor Function Measure Scale-**	• A generic scale which provides a measurement of the effects of muscle weakness in neuromuscular diseases based on posture and movements of the whole body • Target population: o MFM-32 (32 items): 6 to 60 years of age o MFM-20 (20 items): <7 years of age • Items of the MFM-32 and the MFM-20 are classified into 3 dimensions: o D1 Standing and transfers o D2 Axial and proximal motor function o D3 Distal motor function

Test Name	Description and Scoring
20 item (MFM-20)	• A detailed and precise MFM User's Manual permits scoring of the motor capacities of each patient • Scoring: o Each item scored from 0 to 3 (0=cannot initiate the task or maintain the starting position, 1- performs the task partially, 2=performs the task incompletely or imperfectly [compensatory, uncontrolled or slow], 3=completes the task fully and normally) o MFM-32 range: 0 to 96 o MFM-20 range: 0 to 60
Upper Limb Module (ULM) and **Revised Upper Limb Module – (RULM)**	• Motor functional assessment designed to assess upper limb function • Target population: ≥30 months of age o Can be used to assess upper limb function in all SMA patients. Particularly useful for assessing patients at the weak end of the spectrum with low gross motor function scores. • ULM contains 9 items • RULM contains 20 items (19 scored) • Scoring o Each item is scored from 0 to 2 (0=unable to achieve independently, 2=normal with no difficulties) o ULM range: 0 to 18 o RULM range: 0 to 37 (item I can only be scored as 0=unable or 1=able to complete)
Bayley Scales of Infant and Toddler Development-Third Edition (BSID-III, Bayley-III)	• Assessment used to identify developmental delay in infants and toddlers • Target population: 1 month to 42 months of age • Proprietary; limited information available • Consists of five scales: o Three scales (cognitive, language, motor) utilize developmental play tasks administered individually over 45-60 minutes, while the remaining two (social-emotional and adaptive behavior) are based on caretaker responses o Cognitive (91 items) ▪ Evaluating sensorimotor development, exploration and manipulation, object relatedness, concept information and memory o Language (97 items) - Receptive (49 items) and Expressive (48 items) Communication ▪ Pre-verbal behaviors/communication, vocabulary development, social referencing, verbal comprehension, morphological development o Motor (138 items) – Fine (66 items) and Gross Motor (72 item) function ▪ Motor planning and speed, visual tracking, grasping, manipulation, movement of limbs and torso, static positioning (sitting/standing), balance o Social-Emotional ▪ Self-regulation and interest, engaging others, using emotions and emotional signals or gestures to solve problems o Adaptive Behavior ▪ Caregiver information from Adaptive Behavior Assessment System-Second addition includes skill areas such as communication, community use, self-care, pre-academics, social, health and safety, leisure, self-direction, motor • Scoring o Scoring unclear; proprietary; limited information available • Cost/kit (includes 25 booklets, tests, forms, reports): $1,185
Bayley Scales of	• Proprietary; limited information available; published 12/2019

Test Name	Description and Scoring
Infant and Toddler Development-Third Edition (BSID-IV, Bayley-IV)	• Target population: age 16 days to 42 months • Completion time 15 to 25 minutes • Scores/Interpretation by age • Scoring: o Scoring unclear; proprietary; limited information available • Cost/kit (includes 25 booklets, tests, forms, reports): $1,290
Other Assessments	• Six Minute Walk Test (6MWT) • 9-Hole Peg Test • Weight-for-age, length-for-age, weight-for-length/height, head circumference-for-age percentiles (based on WHO 2019 standards) • Respiratory support (e.g., need for ventilation, invasive vs non-invasive) • Nutritional support (e.g., need for tube feedings, ability to swallow oral/solid foods) • SMA Independence Scale (SMAIS) • SMA Functional Rating Scale (SMA-FRS) • Pediatric Evaluation of Disability Inventory – Computer Adaptive Test (PEDI-CAT)

Zolgensma® Monitoring Program

1) PA Review
   - PA will be reviewed based on the established PA criteria.
   - Initial review by operational pharmacist. If any information required for PA approval is missing, outreach should be made to the prescriber's office prior to forwarding to CR.
     - Note: If baseline functional assessments and/or use of other SMA agents are not provided on the PA, it is not a reason for denial. CR will gather additional information during followup if applicable.
   - Final decision by CR after consultation with DUR management and the OCA pharmacy team.

2) CR sends PA decision to operational pharmacist who processes the request through MMIS.

3) Operational pharmacist then forwards the decision details to CR for outreach.
   - CR outreaches to the prescriber's office to inform them of the decision
     - For approvals, attempt should be made to confirm ALL of the following:
       - Planned (or exact) administration date, if known
       - General principles of the monitoring program, including requirements for yearly followups for five years, and information that will be collected (e.g., survival, ventilator/respiratory assistance used, functional assessments and past/current use of other SMA agents)
       - If baseline functional assessments were not provided on the PA, CR should discuss with the office how the member will be monitored on an ongoing basis. Assessments may include motor milestones reached and/or functional rating scales (e.g., CHOP-INTEND, HFMSE, RHS, RULM, etc.). Use of a specific test is not required and may vary from patient to patient. Generally, the same tests should be used over time, if applicable, based on the patients age and/or functional status.
       - If past/current use of other SMA agents were not provided on the PA request, CR should confirm with the office if other SMA agents (e.g., Spinraza®) have been/are currently being used and if use will continue after administration of Zolgensma®.

- For denials, office should be informed of information needed for approval. If the member would not qualify for Zolgensma® therapy based on the established criteria, this should be specifically stated (appeal rights should be mentioned).
    - Note: PA requests should not be denied if only functional assessments or information on past/current use of other SMA agents is missing.

4) After the initial PA decision (approval or denial) for Zolgensma®, the member will automatically be enrolled in the Zolgensma® Monitoring Program.
    - For all requests, CR enters relevant demographic and PA information into the Zolgensma® Monitoring Database (see Tracking Parameters Table below)
        - For denials, information of why PA was denied should be documented.
        - For approvals, planned administration date should be documented.
            - NOTE: If available on PA request, CR should also document any functional assessments and past/current use of other SMA agents at this time. If not available, can request medical records with initial followup (see #6 below).
    - Each subsequent request after a denial should receive its own line in the Zolgensma® Monitoring Database and previous lines would be closed.

5) After an approval, CR creates an instruction flag in Enterprise alerting DUR staff that the member is a candidate for long-term followup after and special considerations may apply.
    - Instruction flag should include guidance that requests for any medication for SMA (e.g., Spinraza®, Zolgensma®) after initial approval of Zolgensma® should be immediately forwarded to CR for case-by-case evaluation.

6) Initial Follow-up
    - Initial followup should occur 30 days-post approval, or 30 days-post planned administration date if provided. If unsuccessful, additional followup attempts should occur every 30 days until successful to a max of 90-days post approval/planned administration date.
    - CR will outreach to prescriber's office to confirm the following and request medical records be submitted to validate:
        - If the medication has been administered and date of administration
        - If baseline functional assessments were not provided on the approved PA request, CR should discuss with the office how the member will be monitored for efficacy. Medical records provided should include baseline assessments if available.
        - If past/current SMA agents used were not provided on the approved PA request, CR should discuss if any SMA agent have been /are currently being used and the plan for ongoing therapy with the other agent. Medical records provided should include information on past/current use of other SMA agents if available.
    - Outreach successful:
        - CR will document exact administration date in the Zolgensma® Monitoring Database
        - If medication not yet administered, CR will document one of the following:
            - If no longer planning to administer, PA should be end-dated and CR will document the reason in the Zolgensma® Monitoring Database. Medical records are not required.
            - If still planning to administer, planned date (if available) should be documented/updated. Continued followup should occur at 60 days- and 90 days-post approval as needed. If planned date is beyond 90 days (i.e., PA expired), PA may be extended if PA criteria is still met (e.g., age <2).

        - CR will document any baseline functional assessments and/or past/current use of other SMA agents, if applicable.
- Outreach unsuccessful:
    - If unsuccessful after 90 days-post approval, a formal request for the member's complete medical records will be made.*
    - CR will evaluate medical records to determine if and when medication was administered.
        - If administered, CR will document the exact administration date in the Zolgensma® Monitoring Database
        - If not administered, CR will document that the medication has not been administered. If provided in the medical record, CR will document the reason for no longer planning to administer in the Zolgensma® Monitoring Database". If not provided, CR will document "unable to confirm" under reason.
    - CR will evaluate medical records for any baseline functional assessments, and/or past/current use of other SMA agents, if applicable.

7) Yearly Followup - Clinical Outcome Measures
- Clinical outcomes for each member will be collected by CR every year, for up to five years after administration of Zolgensma®.
- **Outcomes <u>MUSB BE</u> assessed for all members at the start of every calendar year** (approximately January 1st [potentially earlier if additional time is needed]), regardless of when Zolgensma was administered.
    - NOTE: Because events must be evaluated at the beginning of each calendar year, there would be six yearly followups for each member to cover the five year period. Example:

Administration Date: 6/1/2020		**Covering Events**	
Evaluation End-date: 6/1/2025	**Followup Date**	**From**	**To**
Yearly Followup 1	1/1/2021	06/01/2020	12/31/2020
Yearly Followup 2	1/1/2022	01/01/2021	12/31/2021
Yearly Followup 3	1/1/2023	01/01/2022	12/31/2022
Yearly Followup 4	1/1/2024	01/01/2023	12/31/2023
Yearly Followup 5	1/1/2025	01/01/2024	12/31/2024
Yearly Followup 6	1/1/2026	01/01/2025	06/01/2025

- Each followup will evaluate the following:
    - Death
    - Need for permanent invasive ventilation
    - Functional Assessments
        - If a functional assessment is no longer measured based on patient-specific factors (e.g., CHOP-INTEND score is for infants only), CR will document "no longer being measured"
        - If new functional assessments are added based on patient-specific factors, these should be included in the monitoring program.
    - Past/current use of other SMA agents
- Review will begin with MassHealth Pharmacy and Medical databases, as applicable.
    - If needed, outreach to the prescriber's office will be conducted to confirm any outstanding information via submission of medical records. If outreach is unsuccessful, a formal request for the member's medical records will be made.*
- CR will document outcomes and assessment dates in the Zolgensma® Monitoring Database

*Supporting medical records will be saved as a PDF document in a protected folder on the MHDUR network. A note in enterprise will be added each time additional records are submitted.

8) Upon receipt and evaluation of medical records, DUR will send OCA documentation of whether the medication has been effective or has not been effective based on the established agreement.

Zolgensma Monitoring Program Tracking Parameters	
PA Submission	• PA Number • PA Decision • PA Decision Date • PA Date of approval • Reason for denial (if denied) • Member name • Member identifier (MMIS ID) • Member date of birth • Member coverage status (i.e., PCC, FFS, or ACO-B) • Prescriber name • Prescriber specialty • Affiliated facility • Office number • Office contact (if applicable) • SMA Type • SMN2 copies • Anticipated administration date (approvals only) • Baseline outcome measures and assessment date o Death* o Need for permanent invasive ventilation† • Any baseline functional assessments, including date of assessment and score, if applicable (not required for PA approval)‡ • Past/current use of other SMA agents, including if plan is to continue other SMA agents (not required for PA approval)§
Initial Followup	• Administration Date • Any baseline functional assessments, including date of assessment and score, if applicable, if not previously provided‡ • Past/current use of other SMA agents, including if plan is to continue other SMA agents, if not previously provided§
Annual Follow-Up	• Primary clinical effectiveness parameters and assessment date o Death* o Need for permanent invasive ventilation† • Any functional assessments, including date of assessment and score, if applicable (including any new measures)‡ • Past/current use of other SMA agents (including any new agents started)§

*Death defined as: permanent cessation of all vital functions of a member due to his or her underling disease of SMA

†Permanent invasive ventilation defined as: Positive pressure ventilation applied via an endotracheal or tracheotomy tube due to SMA disease progression

‡Functional tests utilized by the prescriber may vary from member to member depending on patient specific factors. Use of a specific functional test or tests are not required.

§Should include any FDA-approved agents or investigational agents received as part of a clinical trial

Clinical Background Information and References

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
12/1/2020	9.075 Spinal Muscular Atrophy Policy retired, separated Zolgensma into its own policy; criteria aligned with MH Unified Formulary Policy	1/1/2020	P&T Committee

Next Review Date2021

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and

other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.