Serious Reportable Events and Provider Preventable Conditions Payment Policy

Policy

Consistent with state and federal guidelines, the Plan does not reimburse providers for services that are attributable to Serious Reportable Events (SREs), or Provider Preventable Conditions (PPCs). The list of PPCs and SREs in this policy are subject to change.

Definitions

Serious Reportable Event (SRE): An event that occurs on premises covered by a hospital's license that results in an adverse patient outcome, is clearly identifiable and measurable, usually, or reasonably preventable, and of a nature such that the risk of occurrence is significantly influenced by the policies and procedures of the hospital. An SRE is an event that is designated as such by the Massachusetts Department of Public Health (MA DPH) and identified by EOHHS. **The MA DPH has defined SREs to meet the National Quality Forum's definition of such events**.

Provider Preventable Condition (PPC): A condition that meets the definition of a "Health Care Acquired Condition (HCAC)" or an "Other Provider Preventable Condition (OPPC)" as defined by the Centers for Medicare & Medicaid Services (CMS) in federal regulations at 42 CFR 447.26(b). "

Health Care Acquired Condition (HCAC): A condition occurring in any inpatient hospital setting, which Medicare designates as hospital acquired conditions (HACs), pursuant to Section 1886(d)(4)(D)(iv) of the Social Security Act (SSA) (as described in Section 1886(d)(4)(D)(ii) and (iv) of the SSA), *with the exception of* deep vein thrombosis (DVT)/pulmonary embolism (PE) following total knee or total hip replacement in pediatric (under 21 years) and obstetric patients. The list of HCACs is subject to change as a result of revisions to the list of HACs made by CMS.

For Hospital Acquired Conditions, refer to the Hospital Acquired Conditions Payment Policy.

Other Provider Preventable Condition (OPPC): A condition occurring in any health care setting that meets criteria specified in 42 CFR 447.26(b). OPPCs are further divided into two subcategories: (1) "National Coverage Determinations (NCDs);" and (2) "Additional Other Provider Preventable Conditions."

(1) National Coverage Determinations (NCDs): The NCDs are mandatory OPPCs under 42 CFR 447.26(b) and consist of the following conditions that occur in any health-care setting:
   a. Surgical or other invasive procedure performed on the wrong body part
   b. Surgical or other invasive procedure performed on the wrong patient
   c. Wrong surgical or other invasive procedure performed on a patient

(2) Additional Other Provider Preventable Conditions (Additional OPPCs): Additional OPPCs are state-defined OPPCs that meet the requirements of 42 CFR 447.26(b).

Serious Adverse Drug Event (SADE): Any untoward, preventable medical occurrence associated with the use of a controlled substance, as defined in M.G.L. c. 94C, § 1, in humans that results in any of the following outcomes:

a) death;
b) a life-threatening outcome;
c) inpatient hospitalization or prolongation of existing hospitalization;
d) a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions; or
e) a congenital anomaly or birth defect;

provided, however, that adverse medical occurrences directly associated with the use of a controlled substance in humans that may not immediately result in one of the outcomes listed in 105 CMR 130.332: Serious Adverse Drug Event (SADE) (a) through (e) may be considered a serious adverse drug event when they develop into or result in any of the outcomes listed in 105 CMR 130.332: Serious Adverse Drug Event (SADE) (a) through (e).

List of Serious Reportable Events (SREs) and Provider Preventable Conditions (PPCs)

The table below may be used as a guide to determine whether an event may meet one of the definitions above and therefore would be subject to reporting and or other requirements described in this payment policy. Providers should check federal and state guidance for the most up-to-date listings.

Condition or Event	PPC HCAC	PPC OPPC	PPC NCD	SRE
SURGICAL OR INVASIVE PROCEDURE EVENTS				
Surgery or other invasive procedure performed on the wrong site (140.7)			X	X
Surgery or other invasive procedure performed on the wrong patient (140.8)			X	X
Wrong surgical or other invasive procedure performed on a patient (140.6)			X	X
Unintended retention of a foreign object in a patient after surgery or other invasive procedure	X			X
Intraoperative or immediately postoperative/post-procedure death in an ASA Class 1 patient		X		X
Surgical site infection, mediastinitis following coronary artery bypass graft (CABG)	X			
Surgical site infection following certain orthopedic procedures: a) spine b) neck c) shoulder d) elbow	X			
Surgical site infection following bariatric surgery for obesity: a) laparoscopic gastric bypass b) gastroenterostomy c) laparoscopic gastric restrictive surgery	X			
Surgical site infection (SSI) following Cardiac Implantable Electronic Device (CIED) procedures	X			
Iatrogenic pneumothorax with venous catheterization	X			
Deep vein thrombosis (DVT)/pulmonary embolism (PE) following certain orthopedic procedures: a) total knee replacement b) hip replacement Note: This HCAC category does not apply to pediatric (under 21 years of age) or obstetric patients.	X			
PRODUCT OR DEVICE EVENTS				
Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the healthcare setting		X		X
Patient death or serious injury associated with the use or function of a device in patient care, in which the device is used or functions other than as intended		X		X
Patient death or serious injury associated with intravascular	X			X

air embolism that occurs while being cared for in a healthcare setting				
PATIENT PROTECTION EVENTS				
Discharge or release of a patient/resident of any age, who is unable to make decisions, to other than an authorized person				X
Patient death or serious injury associated with patient elopement (disappearance)		X		X
Patient suicide, attempted suicide, or self-harm that results in serious injury, while being cared for in a healthcare setting		X		X
CARE MANAGEMENT EVENTS				
Patient death or serious injury associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration)		X		X
Patient death or serious injury associated with unsafe administration of blood products	X			X
Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare setting		X		X
Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy		X		X
Patient death or serious injury associated with a fall while being cared for in a healthcare setting				X
Any Stage 3, Stage 4, and unstageable pressure ulcers acquired after admission/presentation to a healthcare setting	X	X		X
Artificial insemination with the wrong donor sperm or wrong egg				X
Patient death or serious injury resulting from the irretrievable loss of an irreplaceable biological specimen		X		X
Patient death or serious injury resulting from failure to follow up or communicate laboratory, pathology, or radiology test results		X		X
Manifestations of poor glycemic control that include a) diabetes ketoacidosis b) nonketotic hyperosmolar coma c) hypoglycemic coma d) secondary diabetes with ketoacidosis e) secondary diabetes with hyperosmolarity	X			
Falls and trauma related to a) fractures b) dislocations c) intracranial injuries d) crushing injuries e) burns f) other injuries		X		
Catheter-associated urinary tract infection (UTI)	X			
Vascular Catheter-Associated Infection	X			
ENVIRONMENTAL EVENTS				
Patient or staff death or serious injury associated with an electric shock in the course of a patient care process in a healthcare setting				X
Any incident in which systems designated for oxygen or other gas to be delivered to a patient contains no gas, the wrong gas, or are contaminated by toxic substances				X
Patient or staff death or serious injury associated with a burn				X

incurred from any source in the course of a patient care process in a healthcare setting				
Patient death or serious injury associated with the use of physical restraints or bedrails while being cared for in a healthcare setting		X		X
RADIOLOGIC EVENTS				
Death or serious injury of a patient or staff associated with the introduction of a metallic object into the MRI area		X		X
POTENTIAL CRIMINAL EVENTS				
Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider				X
Abduction of a patient/resident of any age				X
Sexual abuse/assault on a patient or staff member within or on the grounds of a healthcare setting				X
Death or serious injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of a healthcare setting		X		X

Reimbursement

The Plan will not reimburse for SREs based on those events included in, the NQF table of reportable events to which 105 CMR 130.332 applies (including PPCs and SADEs that are SREs).

The Plan will not reimburse for PPCs in violation of the federal requirements, under Section 2702 of the Patient Protection and Affordable Care Act (Pub. L. 111-148) (the ACA) and federal regulations at 42 CFR 447.26.

No reduction in payment for a PPC will be imposed on a provider when the condition defined as a PPC for a particular patient existed prior to the initiation of treatment for that patient by that provider (42 CFR 447.26(c)(2)).

The Plan does not reimburse providers for readmissions or follow up care related to an SRE or PPC, remediation or complication due to an SRE or PPC within 30 days of discovery of the event with the same provider or a provider owned by the same parent organization.

Referral/notification/prior authorization requirements

Providers must follow Federal and State requirements for the reporting of an SRE, SADE, and PPC.

SRE Reporting

As specified in the requirements of 105 CMR 130.332, Providers must file an initial written report with the Department of Public Health within seven (7) days of discovery of a Serious Reportable Event and notify the member or representative about the occurrence.

Providers are further required, no later than 30 days after the date of reporting of the SRE, (including a SADE and PPC that are SREs), to make the preventability determination, and submit a follow-up report to the DPH and Fallon Health, to the attention of the Fallon Health Director of Provider Relations via fax 508-368-9902.

The 30 day follow up report must include at a minimum, the following: 1. narrative description of the SRE; 2. analysis and identification of the root cause of the SRE; 3. analysis of the preventability criteria required by 105 CMR 130.332(C)(1); 4. description of the corrective actions developed, implemented and to be monitored by the hospital following discovery of the SRE; and 5. whether the hospital intends to charge or seek reimbursement for services provided by the hospital as a result of the SRE.

Carelon is the Plan's behavioral health vendor. SREs related to behavioral health care must be reported to Carelon at 1-888-421-8861.

PPC Reporting

As specified in the requirements under Section 2702 of the Patient Protection and Affordable Care Act (Pub. L. 111-148) (the ACA) and federal regulations at 42 CFR 447.26, Providers must report the occurrence of a PPC and all PPC-related services through claims submissions.

If a PPC is also an SRE, Providers must report the SRE as specified in the requirements of 105 CMR 130.332.

SADE Reporting

As specified in the requirements of 105 CMR 130.332, Providers must file an initial written report with the Department of Public Health within seven (7) days of discovery of a medication error that occurs or occurred on the premises of the hospital, and that meets the definition of a SADE. A hospital shall report the SADE to the Department of Public Health as specified in guidelines.

If a SADE also is an SRE, the hospital shall also comply with the requirements of 105 CMR 130.332(B), (C) and (D).

Upon first discovering, through diagnostic evaluation and assessment of an individual patient, that a SADE has resulted from a patient's use, consumption, or interaction with any pharmaceutical or drug preparation, a hospital must report the event to the federal MedWatch Program, as well as the pharmacy from which the drug was produced or compounded in addition to all other reporting requirements.

Billing/coding guidelines

Providers must immediately suspend or rescind any SRE/PPC related claims to the Plan pending the preventability determination and notification requirements.

All claims related to an SRE or PPC must contain the appropriate Present on Admission (POA) as described in Appendix V: MassHealth Billing Instructions for Provider Preventable Conditions, Mass.gov.

Non-payment for SREs, SADE's, or PPCs will not prevent member access to health care services.

Providers are not permitted to bill members related to non-payment of SREs, SADE's or PPCs.

The Plan reserves the right to audit both professional and facility medical records regarding SREs, SADE's or PPCs.

Any dispute(s) arising between the hospital and the Plan shall be addressed through the provider appeals process.

The following references were used in the creation of this policy:

- National Quality Forum's (NQF)
- CMS-Centers for Medicare & Medicaid Services Hospital Acquired Conditions
- EOHHS-Executive Office of Health and Human Services Serious Reportable Events
- MassHealth All Provider Manuals Appendix U
- MassHealth All Provider Manuals Appendix V
- Department of Public Health 105 Mass. Reg. 130.332 Serious Reportable Events (SREs) and Serious Adverse Drug Events (SADE)
- Code of Federal Regulations (CFR) 42 CFR 447.26, 42 CFR 434.6(a)(12), 42 CFR 438.3(g)
- Massachusetts General Law- M.G.L. c. 94C, § 1

- Section 2702 of the Patient Protection and Affordable Care Act (Pub. L. 111-148),
- MassHealth Transmittal Letter CHC-95 June 2012

Place of service

This policy applies to services rendered in all settings.

Policy history

Origination date:	01/01/09
Previous revision date(s):	07/01/09 – changed policy name from Never Events to Serious Reportable Events; updated language in the Policy, Definitions, Reimbursement, and Referral/notification/preauthorization requirements sections. 09/01/2012 - Moved to new format for benefit application list and added language about post-payment audits at the end of the policy. 03/01/2016 - Annual review and updated to new Plan template.
Connection date and details:	January 2017 – Annual review. April 2018 – Updated National Quality Forum's (NQF) SRE's. April 2019 – Annual review, no updates. April 2020 – Annual review, no updates. April 2023 - MassHealth ACO required elements updated throughout.

The criteria listed above apply to Fallon Health plan and its subsidiaries. This payment policy has been developed to provide information regarding general billing, coding, and documentation guidelines for the Plan. Even though this payment policy may indicate that a particular service or supply is considered covered, specific provider contract terms and/or member individual benefit plans may apply, and this policy is not a guarantee of payment. The Plan reserves the right to apply this payment policy to all of the Plan companies and subsidiaries. The Plan routinely verifies that charges billed are in accordance with the guidelines stated in this payment policy and are appropriately documented in the medical records. Payments are subject to post-payment audits and retraction of overpayments.