

Serious Reportable Events & Provider Preventable Conditions

Policy

Mass General Brigham Health Plan systematically monitors and evaluates patient safety concerns related to our members. Mass General Brigham Health Plan reviews, investigates and responds to quality of care concerns and to mandated reportable quality events. This policy is organized based upon mandated reportable quality events which includes any Provider Preventable Condition (PPC), Serious Reportable Event (SRE), and Serious Adverse Drug Events (SADE). This policy applies to outpatient facilities, inpatient hospitals and all other providers.

Policy Definition

Serious Reportable Event (SRE): An event that occurs on the premises of a provider's site that results in an adverse patient outcome; is clearly identifiable and measurable; usually or reasonably preventable; and is of a nature such that the risk of occurrence is significantly influenced by the policies and procedures of the provider. An SRE is an event that is designated as such by the Department of Public Health (DPH) and identified by EOHHS (Executive Office of Health and Human Services). Mass General Brigham Health Plan utilizes the National Quality Forum's (NQF) definition of SREs.

Provider Preventable Condition (PPC) is an umbrella term for conditions that meet the definition of a "health care-acquired condition" or an "other provider preventable condition" as defined by the Centers for Medicare & Medicaid Services (CMS) in federal regulations at 42 CFR .447.26(b).

- Hospital Care Acquired Conditions (HCAC): The Deficit Reduction Act of 2005 requires facilities to identify conditions that are:
- High cost or high volume or both
- Result in the assignment of a case to a DRG that has a higher payment when present as a secondary diagnosis, and
- Could reasonably have been prevented through the application of evidence-based guidelines.

Other Provider Preventable Conditions (OPPC) that meet the requirements of an "other provider

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preventable condition” pursuant to 42 CFR.447.26 (b). OPPCs may occur in any health-care setting and are divided into two sub-categories.

- National Coverage Determinations (NCDs) NCDs are mandatory OPPCs under 42 CFR. 447.26(b) and mean any of the following conditions that occur in any health-care setting:
 - Wrong surgical or other invasive procedure performed on a patient
 - Surgical or other invasive procedure performed on the wrong body part
 - Surgical or other invasive procedure performed on the wrong patient
- For each of a through c above, the term “surgical or other invasive procedure” is as defined in CMS Medicare guidance on NCDs. 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). 7/14/

Provider Reporting Requirements

SREs/SADEs/PPCs Events: Mass General Brigham Health Plan requires that providers report SREs, SADEs, and PPCs as follows:

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For Events that are only SREs:

Providers are required to report SREs to the Department of Public Health (DPH) by submitting a Serious Incident Report Form within seven (7) and thirty (30) calendar days from the date the event took place. The 30-day SRE report should include the root cause analysis of the event, determination of preventability, and corrective measures (as applicable)

For medical events, Mass General Brigham Health Plan requires that providers submit the SRE form via fax at 617-526-1916 within 7 and 30 calendar days from the date the event took place.

For events related to behavioral healthcare, Mass General Brigham Health Plan requires that BH providers submit the SRE form 7/30 Day SRE DPH report to our Behavioral Health's Partner Optum at Fax # 844-814-5698.

For Events that are SADEs or Both and SRE and SADEs

Providers are required to report SADEs to the DPH as specified in the guidelines of the Department, within seven (7) days of the date of discovery of a medication error that occurs or occurred on the premises of the provider and meets the definition of SADE.

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

As defined by the 105 CMR 130.332 regulations, 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 provider 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.

For Events that are both an SRE and PPC:

Providers are required to report PPCs through claims submission 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. MassHealth providers must report PPCs to MassHealth agencies.

For any PPC that is also an SRE (please see table below for a list of PPCs and SREs), as designated by the DPH pursuant to its regulations at 105 CMR 130.332, a provider must not only notify Mass General Brigham Health Plan (for medical events) or Optum (for BH events) by claims submission, but must also

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report the occurrence of the SRE or the PPC as an SRE to DPH, and submit the documented 7 and 30 day SRE report to Mass General Brigham Health Plan or Optum as described above.

Present on Admission (POA) Indicator and Modifier

Present on Admission (POA) criteria for Inpatient Hospitals:

Services directly related to the PPC: submit a no-pay claim on bill type 110, reason code 11, and Present on Admission (POA) indicator for reporting purposes only as indicated below:

POA Indicator	Service Description
Y	yes (present at the time of inpatient admission)
N	no (not present at the time of inpatient admission)
U	unknown (documentation is insufficient to determine if condition was present at the time of admission)
W	clinically undetermined (provider is unable to clinically determine whether condition was present on admission)
1 or Blank	(on electronic claims) or blank (for paper claims) = exempt from POA reporting

Modifier Criteria for Outpatient Providers, Freestanding ambulatory surgery centers

Services directly related to the PPC: submit a no-pay claim on bill type 130 and modifiers and reason code 11 for reporting purposes only as indicated below:

Modifier	Description
PA	Surgery on wrong body part
PB	Surgery on wrong patient
PC	Wrong surgery on patient

All Other Providers

Submit a separate professional claim to identify NCD-related services using the applicable NCD modifier and Reason 11.

NCD Description	Diagnosis Code	Modifiers
Surgical or other invasive procedure performed on the wrong body part	Y65.53 (Performance of correct procedure (operation) on wrong side/body part)	PA

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Surgical or other invasive procedure performed on the wrong patient	Y65.52 (Performance of procedure (operation) on patient not scheduled for surgery)	PB
Wrong surgical or other invasive procedure performed on a patient	Y65.51 (Performance of wrong procedure (operation) on correct patient)	PC

If non-NCD-related services submit a second professional claim to bill for the non-NCD-related services.

[General Coding and Billing](#)

Provider Reimbursement and Payment Guidelines

Providers are reimbursed according to the plan’s network provider reimbursement or contracted rates. Claims are subject to payment edits that are updated at regular intervals.

Covered services are defined by the member’s benefit plan. The manner in which covered services are reimbursed are determined by the Mass General Brigham Health Plan Payment Policy and by the provider’s agreement with Mass General Brigham Health Plan. Member liability amounts may include, but are not limited to, copayments, deductible, and/or co-insurance, and will be applied dependent upon the member’s benefit plan. Various services and procedures require referral and/or authorization. Referral and authorization requirements can be located [here](#).

Please reference procedure codes from the current CPT, HCPCS Level II, and ICD-10-CM manuals, as recommended by the American Medical Association (AMA), the Centers for Medicare & Medicaid Services (CMS), and the American Hospital Association. CMS and the AMA revise HIPAA medical codes on a pre-determined basis, including changes to CPT, HCPCS, and ICD-10 codes and definitions.

Please refer to the CMS or CPT guidelines for requisite modifier usage when reporting services. The absence or presence of a modifier may result in differential claim payment or denial.

Mass General Brigham Health Plan reviews claims to determine eligibility for payment. Services considered incidental, mutually exclusive, integral to the primary service rendered, or part of a global allowance, are not eligible for separate reimbursement. Please refer to [Coding Provider Payment Guidelines](#) for more information.

All claims are subject to audit services and medical records may be requested from the provider. In the event of an SRE or PPC is identified as preventable Mass General Brigham Health Plan will request an

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itemized bill within 5-10 business days from the date of this via 617-526-1950 to “Payment Policy Data Integrity Services (PPDIS).

Mass General Brigham Health Plan Reimbursement

Mass General Brigham Health Plan reimburses eligible providers who accept transferred patients for post-event care at another institution or under the care of another physician. Providers are strictly prohibited to collect and/or bill Mass General Brigham Health Plan members for copayments, coinsurance, deductible charges, if any, including attempts to balance bill Mass General Brigham Health Plan members for events and/or post-event related services, which are designated as ineligible for payment.

Providers are reimbursed according to the plan's network provider reimbursement or contracted rates. Claims are subject to payment edits that are updated at regular intervals.

Mass General Brigham Health Plan Does Not Reimburse

In accordance with Federal and State regulations, Mass General Brigham Health Plan does not reimburse services associated with SREs or PPCs. When payment has been made for services associated with an SRE or PPC, Mass General Brigham Health Plan is entitled to retract reimbursement previously made to the Provider. Mass General Brigham Health Plan reserves the right to apply regulations and guidelines promulgated by CMS that relate to SREs to support Mass General Brigham Health Plan actions in the application of state specific determinations.

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

List of Serious Reportable Events (SREs) and Provider Preventable Conditions (PPCs) (*1)

CONDITION OR EVENT	PPC HCAC	PPC OPPC	PPC NCD	SR E
SURGICAL EVENTS				
Surgery or other invasive procedure performed on the wrong site			✓	✓
Surgery or other invasive procedure performed on the wrong patient			✓	✓
Wrong surgery or other invasive procedure performed on the patient			✓	✓

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CONDITION OR EVENT	PPC HCAC	PPC OPPC	PPC NCD	SR E
Intraoperative or immediate postoperative death of an otherwise healthy patient (ASA class 1)		✓		✓
Surgery or other invasive procedure performed on the wrong body part			✓	✓
Unintended retention of a foreign object after surgery	✓			✓
Surgical Site Infection Following: <ul style="list-style-type: none"> -- Cardiac Implantable Electronic Device -- Coronary Artery Bypass Graft (CABG) (includes mediastinitis) -- Certain Orthopedic Procedures <ul style="list-style-type: none"> - Spine - Neck - Shoulder - Elbow -- Bariatric Surgery for Obesity <ul style="list-style-type: none"> - Laparoscopic Gastric Bypass - Gastroenterostomy - Laparoscopic Gastric Restrictive Surgery 	✓			
PRODUCT OR DEVICE EVENTS				
Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the healthcare setting		✓		✓
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		✓		✓
Patient death or serious injury associated with intravascular air embolism that occurs while being cared for in a healthcare setting	✓			✓
PATIENT PROTECTION EVENTS				
Patient suicide or attempted suicide while being cared for in a health care facility		✓		✓
Discharge or release of a patient/resident of any age, who is unable to make decisions, to other than an authorized person				✓
Patient death or serious injury associated with patient elopement (disappearance)		✓		✓

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CONDITION OR EVENT	PPC HCAC	PPC OPPC	PPC NCD	SR E
Patient suicide, attempted suicide, or self-harm that results in serious injury, while being cared for in a healthcare setting		✓		✓
CARE MANAGEMENT EVENTS				
Deep Vein Thrombosis/Pulmonary Embolism Following Certain Orthopedic Procedures: -- Total Knee Replacement -- Hip Replacement <i>Note: This HCAC category does not apply to pediatric (under 21 years of age) or obstetric patients.</i>	✓			
Iatrogenic Pneumothorax with Venous Catheterization	✓			
Patient death or serious injury associated with unsafe administration of blood products	✓			✓
Stage III, IV and Unstageable Pressure Ulcers	✓	✓		✓
CONDITION OR EVENT	PPC HCAC	PPC OPPC	PPC NCD	SR E
Manifestations of Poor Glycemic Control - Diabetic Ketoacidosis - Nonketonic Hyperosmolar Coma - Hypoglycemic Coma - Secondary Diabetes with Ketoacidosis - Secondary Diabetes with Hyperosmolarity	✓			
Vascular Catheter-Associated Infection	✓			
Catheter-Associated Urinary Tract Infection (UTI)	✓			
Patient death or serious associated with a medication error (for example, errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration)		✓		✓
Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy while being cared for in a health care facility		✓		✓
Death or serious injury of a neonate associated with labor and delivery in a low-risk delivery		✓		✓
Patient death or serious injury resulting from the irretrievable loss of an irreplaceable biological specimen		✓		✓

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CONDITION OR EVENT	PPC HCAC	PPC OPPC	PPC NCD	SR E
Patient death or serious injury resulting from failure to follow up or communicate laboratory, pathology, or radiology test results		✓		✓
Patient death or serious injury associated with a fall while being cared for in a healthcare setting	✓			✓
Artificial insemination with the wrong donor sperm or wrong egg				✓
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				✓
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				✓
Patient or staff death or serious injury associated with a burn 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		✓		✓
RADIOLOGIC EVENTS				
Death or serious injury of a patient or staff associated with the introduction of a metallic object into the MRI area		✓		✓
POTENTIALLY CRIMINAL EVENTS				
Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider				✓
Abduction of a patient/resident of any age				✓
Sexual abuse/assault on a patient or staff member within or on the grounds of a healthcare setting				✓
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		✓		✓

(*1) Please note that the list above may not be a comprehensive inventory of SREs/PPCs. We recommend providers to review state and federal regulations for a complete listing.

References

[CMS Healthcare Acquired Conditions \(HAC\) ICD-10 Code List](#)
[Commonwealth of Massachusetts, Chapter 305](#)
[Federal Regulation:42 C.F.R.; 434.6\(a\)\(12\)](#)
[Federal Regulation:42 C.F.R.; 438.3\(g\)](#)
[Federal Regulation:42 C.F.R.; 447.26](#)
[DPH Guidance for Reporting SREs: 105 CMR; 130.331: DPH Serious Incident and Accident Reports](#)
[Maine State Health Policy, Title 22, §8753: Mandatory Reporting of Sentinel Events](#)
[MassHealth Billing Instructions for Provider Preventable Conditions \(PPCs\)](#)
[MassHealth Data & Reports on Serious Reportable Event \(SREs\) in Health Care](#)
[MassHealth Other Hospital Quality Payment Initiatives](#)
[MassHealth SRE Reporting Guidance](#)
[National Quality Forum \(NQF\) SRE](#)
[New Hampshire Department of Health and Human Services, Serious Adverse Events](#)
[Rhode Island General Laws Title 23 - Health Care Facilities Hospital Events Reporting](#)
[Rhode Island Did Not Ensure Its Managed-Care Organizations Complied With Requirements Prohibiting Medicaid Payments for Services Related to Provider-Preventable Conditions, A-01-17-00004 \(hhs.gov\)](#)

Publication History

Topic: Serious Reportable Events	Owner: Network Management
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July 26, 2009	<i>Original documentation</i>
January 2, 2011	<i>Reviewed, disclaimer updated</i>
July 1, 2012	<i>Inclusion of Medicaid Provider Preventable Conditions – update to hyperlinks</i>
March 1, 2016	<i>Document restructure; include reference links to billing/coding instruction</i>
January 1, 2019	<i>Document restructure; codes, code descriptor and references updated</i>
May 1, 2020	<i>Updated Policy Definitions Section: Added Serious Adverse Drug Event (SADE) definition. Added a section regarding Provider Reporting Requirements outlining regulatory timeframes and mechanisms to be used by providers (fax, claims) to report these events. Updated Serious Reportable Events (SREs) and Provider Preventable Conditions (PPCs) Crosswalk. Updated Policy References Section to</i>

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include SRE/PPC State and Federal regulations for New Hampshire, Rhode Island and Maine.

January 1, 2023

Document rebrand; updated references

This document is designed for informational purposes only. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization/notification and utilization management guidelines when applicable, adherence to plan policies and procedures, claims editing logic, and provider contractual agreement. In the event of a conflict between this payment guideline and the provider's agreement, the terms and conditions of the provider's agreement shall prevail. Payment policies are intended to assist providers in obtaining Mass General Brigham Health Plan's payment information. Payment policy determines the rationale by which a submitted claim for service is processed and paid. Payment policy formulation takes into consideration a variety of factors including: the terms of the participating providers' contract(s); scope of benefits included in a given member's benefit plan; clinical rationale, industry-standard procedure code edits, and industry-standard coding conventions.

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