

2019 (old version),2020 (new version),Type of Change,Reason for Change,Burden Change

Part D: Coverage Determination,,,,,

2.e. RSC 5 Organization data passes data integrity checks listed below:,"2.e. RSC 5 Organization data passes data integrity checks listed below: Organization data passes data integrity checks listed below: The number of expected counts (e.g., number of members, claims, grievances, procedures) are verified; ranges of data fields are verified; all calculations (e.g., derived data fields) are verified; missing data has been properly addressed; reporting output matches corresponding source documents (e.g., programming code, saved queries, analysis plans); version control of reported data elements is appropriately applied; QA checks/thresholds are applied to detect outlier or erroneous data prior to data submission.□ to the description (column D). In addition added

□[Note: Data Elements 1.A - 1.R relate to Coverage Determinations, Data Elements 2.A □ 2.F relate to Redeterminations, and Data Elements 3.A and 3.B.1 □ 3.B.12 relate to Re-openings]□ for clarification

",Update,Changes consistent with approved 2019 Part D TS & RR.,None

"2.d RSC 4 Terms used are properly defined per CMS regulations, guidance and Reporting Requirements Technical Specifications.

1. Organization properly determines whether a request is subject to the coverage determinations or the exceptions process in accordance with 42 CFR §423.566, §423.578, and the Prescription Drug Benefit Manual Chapter 18, Sections 10 and 30. This includes applying all relevant guidance properly when performing its calculations and categorizations for the above-mentioned regulations in addition to 42 CFR §423.568, §423.570, §423.572, §423.576 and the Prescription Drug Benefit Manual Chapter 18, Sections 40, 50, and 130.

2. Organization properly defines the term "Redetermination" in accordance with Title 42, Part 423, Subpart M §423.560, §423.580, §423.582, §423.584, and §423.590 and the Prescription Drug Benefit Manual Chapter 18, Section 10, 70, and 130. This includes applying all relevant guidance properly when performing its calculations and categorizations.

3. Refer to 42 CFR §423.1978-1986 and Chapter 18, section 120 of the Medicare Prescription Drug Benefit Manual for additional information and CMS requirements related to re-openings.", "2.d RSC 4 Terms used are properly defined per CMS regulations, guidance and Terms used are properly defined per CMS regulations, guidance and Reporting Requirements Technical Specifications.

Organization properly defines the term "Coverage Determinations" in accordance with 42 C.F.R. Part 423, Subpart M, and the Parts C & D Enrollee Grievances, Organization/Coverage Determinations and Appeals Manual. This includes applying all relevant guidance properly when performing its calculations and categorizations.

Organization properly defines the term "Redetermination" in accordance with 42 C.F.R. Part 423, Subpart M, and the Parts C & D Enrollee Grievances, Organization/Coverage Determinations and Appeals Manual. This includes applying all relevant guidance properly when performing its calculations and categorizations. ",Update,Changes consistent with approved 2019 Part D TS & RR.,None

"2.e RSC-5.c 2.D, 2.E, 2.F",2.e RSC-5.c □2.D + 2.E + 2.F□ ,Update,Changes consistent with approved 2019 Part D TS & RR.,None

"RSC-6.g: Excludes coverage determinations (including exceptions) from delegated entities. [Data Element 1.A]

",RSC-6.g: Includes coverage determinations (including exceptions) from delegated entities. [Data Element 1.A],Update,Changes consistent with approved 2019 Part D TS & RR.,None

RSC-14 Organization accurately reports the following information for each redetermination.,RSC-14 Organization accurately reports the following information for each reopened case.,Update,Changes consistent with approved 2019 Part D TS & RR.,None

Part D: Grievances,,,,,

2.e RSC 5 Organization data passes data integrity checks listed below:,"2.e RSC

5 Organization data passes data integrity checks listed below: Organization data passes data integrity checks listed below: The number of expected counts (e.g., number of members, claims, grievances, procedures) are verified; ranges of data fields are verified; all calculations (e.g., derived data fields) are verified; missing data has been properly addressed; reporting output matches corresponding source documents (e.g., programming code, saved queries, analysis plans); version control of reported data elements is appropriately applied; QA checks/thresholds are applied to detect outlier or erroneous data prior to data submission. [Data Elements A-E] to the description.",Update,Changes consistent with approved 2019 Part D TS & RR.,None

"RSC. 6 The number of expected counts (e.g., number of members, claims, grievances, procedures) are verified; ranges of data fields are verified; all calculations (e.g., derived data fields) are verified; missing data has been properly addressed; reporting output matches corresponding source documents (e.g., programming code, saved queries, analysis plans); version control of reported data elements is appropriately", "RSC.6 Organization accurately calculates the total number of grievances, including the following criteria: ",Update,Changes consistent with approved 2019 Part D TS & RR.,None

Part D: DUR,,,,

"RSC 4 a. Applying all relevant guidance to properly establish and implement a care coordination formulary-level cumulative opioid morphine milligram equivalent (MME) threshold point of sale (POS) edit, and if applicable, a hard formulary-level cumulative opioid threshold POS edit, and an opioid naïve days supply POS edit. ", "RSC 4 a. Applying all relevant guidance to properly establish and implement a care coordination formulary-level cumulative opioid morphine milligram equivalent (MME) threshold point of sale (POS) edit, an opioid naïve days supply POS edit, and if applicable, a hard formulary-level cumulative opioid MME threshold POS edit.",Update,Consistent with current technical guidance. ,None

"RSC 4 b. Organization provides documentation that its care coordination safety POS edit, and if applicable, hard MME safety POS edit, and its opioid naïve days supply safety POS edit were properly tested and validated prior to its implementation date.", "RSC 4 b. Organization provides documentation that its care coordination safety POS edit, an opioid naïve days supply POS edit, and if applicable, a hard formulary-level cumulative opioid MME threshold POS edit were properly tested and validated prior to its implementation date.",Update,Consistent with current technical guidance. ,None

RSC 5: Organization data passes data integrity checks listed below:

, "RSC 5: Organization data passes data integrity checks listed below: The number of expected counts (e.g., number of members, claims, grievances, procedures) are verified; ranges of data fields are verified; all calculations (e.g., derived data fields) are verified; missing data has been properly addressed; reporting output matches corresponding source documents (e.g., programming code, saved queries, analysis plans); version control of reported data elements is appropriately applied; QA checks/thresholds are applied to detect outlier or erroneous data prior to data submission",Update,Changes consistent with approved 2019 Part D TS & RR.,None

RSC 5 a.ii. The number of care coordination safety edit claim rejections overridden by the pharmacist at the pharmacy (Data Element D) does not exceed the number of claims rejected due to the care coordination safety edit (Data Element C).,RSC 5 b.ii. The number of care coordination safety edit claim rejections overridden by the pharmacist at the pharmacy (Data Element D) is a value less than or equal to the number of claims rejected due to the care coordination safety edit (Data Element C).,Update,Consistent with current technical guidance. ,None

RSC 5. a. iii. The number of unique beneficiaries with at least one care coordination safety edit claim rejection overridden by the pharmacist at the pharmacy (Data Element F) does not exceed the number of unique beneficiaries with at least one claim rejected due to the care coordination safety edit (Data Element E).,RSC 5. b. iii. The number of unique beneficiaries with at least one care coordination safety edit claim rejection overridden by the pharmacist at the pharmacy (Data Element F) is a value less than or equal to the number of unique beneficiaries with at least one claim rejected due to the care coordination safety edit (Data Element E).,Update,Consistent with current

technical guidance. ,None

RSC 5. b. ii. The number of unique beneficiaries with at least one hard MME safety edit claim rejection that also had a coverage determination or appeal request from hard MME safety edit rejections (Data Element O) does not exceed the number of unique beneficiaries with at least one claim rejected due to the hard MME safety edit (Data Element M).,RSC 5. b.ii. The number of unique beneficiaries with at least one hard MME safety edit claim rejection that also had a coverage determination or appeal request from hard MME safety edit rejections (Data Element O) is a value less than or equal to the number of unique beneficiaries with at least one claim rejected due to the hard MME safety edit (Data Element M).,Update,Consistent with current technical guidance. ,None

RSC 5. b. iii. The number of unique beneficiaries with at least one hard MME safety edit claim rejection with a coverage determination or appeal request from hard MME safety edit rejections that had a favorable (either full or partial) coverage determination or appeal (Data Element P) does not exceed the number of unique beneficiaries with at least one claim rejected due to the hard MME safety edit (Data Element M).,RSC 5. b. iii. The number of unique beneficiaries with at least one hard MME safety edit claim rejection with a coverage determination or appeal request from hard MME safety edit rejections that had a favorable (either full or partial) coverage determination or appeal (Data Element P) is a value less than or equal to the number of unique beneficiaries with at least one claim rejected due to the hard MME safety edit (Data Element M).,Update,Consistent with current technical guidance. ,None

RSC 5. d.iii. The number of unique beneficiaries with at least one opioid naïve days supply safety edit claim rejection that also had a coverage determination or appeal request for an opioid drug subject to the edit (Data Element V) does not exceed the number of unique beneficiaries with at least one claim rejected due the opioid naïve days supply safety edit (Data Element T).,i.iii. The number of unique beneficiaries with at least one opioid naïve days supply safety edit claim rejection that also had a coverage determination or appeal request for an opioid drug subject to the edit (Data Element V) is a value less than or equal to the number of unique beneficiaries with at least one claim rejected due the opioid naïve days supply safety edit (Data Element T).,Update,Consistent with current technical guidance. ,None

"RSC 6. c. iii. Rejected opioid claims are counted at the unique plan, beneficiary, prescriber, pharmacy, drug (strength and dosage form), quantity date of service (DOS) and formulary-level opioid MME POS edit.", "RSC 6. c. iii. Rejected opioid claims are counted at the unique plan, beneficiary, prescriber, pharmacy, drug (strength and dosage form), and quantity date of service (DOS).",Update,Consistent with current technical guidance. ,None

RSC 8.a.iii Includes all coverage determinations or appeals (fully favorable and partially favorable).,RSC 8.a.iii Includes all coverage determinations or appeals requests. ,Update,Consistent with current technical guidance. ,None

RSC 8.b.iii Includes all coverage determinations or appeals (fully favorable and partially favorable).,RSC 8.b.iii Includes all coverage determinations or appeals requests. ,Update,Consistent with current technical guidance. ,None

RSC 9.a. i. The beneficiary's opioid claim is also included in data element O.,RSC 9. a.i. The beneficiary's opioid claim is also included in data element M.,Update,Consistent with current technical guidance. ,None

RSC 9.b.i. The beneficiary's opioid claim is also included in data element V.,RSC 9.b.i. The beneficiary's opioid claim is also included in data element T.,Update,Consistent with current technical guidance. ,None

RSC 10.a.i The beneficiary's opioid claim is also included in data element O.,RSC 10.a.i The beneficiary's opioid claim is also included in data element M.,Update,Consistent with current technical guidance. ,None

RSC 10.b.i The beneficiary's opioid claim is also included in data element V.,RSC 10.b.i The beneficiary's opioid claim is also included in data element T.,Updated,Consistent with current technical guidance. ,None

Properly reports the care coordination safety edit formulary-level cumulative opioid MME threshold reported matches the CY 2019 care coordination safety edit formulary-level cumulative opioid MME threshold submission to CMS via HPMS., "Properly reports the care coordination safety edit formulary-level cumulative opioid MME threshold, provider count, and pharmacy count criteria reported matches the CY 2019 care coordination safety edit formulary-level

cumulative opioid MME threshold submission to CMS via HPMS.",Update,Changes consistent with approved 2019 Part D TS & RR.,None

Part D: MTM,,,,

"RSC 2. A review of source documents (e.g., programming code, spreadsheet formulas, analysis plans, saved data queries, file layouts, process flows) and census or sample data, whichever is applicable, indicates that data elements for each reporting section are accurately identified, processed, and

calculated.", "RSC 2. A review of source documents (e.g., programming code, spreadsheet formulas, analysis plans, saved data queries, file layouts, process flows) and census data, whichever is applicable, indicates that data elements for each reporting section are accurately identified, processed, and

calculated.",Update,Changes consistent with approved 2019 Part D TS & RR.,None

RSC 5. Organization data passes data integrity checks listed below:,"RSC 5.

Organization data passes data integrity checks listed below: The number of expected counts (e.g., number of members, claims, grievances, procedures) are verified; ranges of data fields are verified; all calculations (e.g., derived data fields) are verified; missing data has been properly addressed; reporting output matches corresponding source documents (e.g., programming code, saved queries, analysis plans); version control of reported data elements is appropriately applied; QA checks/thresholds are applied to detect outlier or erroneous data prior to data submission.",Update,Changes consistent with approved 2019 Part D TS & RR.,None

"RSC 6. The number of expected counts (e.g., number of members, claims, grievances, procedures) are verified; ranges of data fields are verified; all calculations (e.g., derived data fields) are verified; missing data has been properly addressed; reporting output matches corresponding source documents (e.g., programming code, saved queries, analysis plans); version control of reported data elements is appropriately applied; QA checks/thresholds are applied to detect outlier or erroneous data prior to data submission. Applicable

Reporting Section Criteria:","RSC-6: Organization accurately identifies data on

MTM program participation and uploads it into HPMS, including the following

criteria:","Update,Changes consistent with approved 2019 Part D TS & RR.,None

"RSC-10.c: Properly identifies and includes the qualified provider who performed the initial CMR; if more than one CMR is received, the qualified provider for only the initial CMR is reported. The qualified provider must be reported as one of the following: Physician, Registered Nurse, Licensed Practical Nurse, Nurse Practitioner, Physician's Assistant, Local Pharmacist, LTC Consultant

Pharmacist, Plan Sponsor Pharmacist, Plan Benefit Manager (PBM) Pharmacist, MTM Vendor Local Pharmacist, MTM Vendor In-house Pharmacist, Hospital Pharmacist, Pharmacist □ Other, Supervised Pharmacy Intern, or Other.", "RSC-10.c: Properly

identifies and includes the qualified provider who performed the initial CMR; if more than one CMR is received, the qualified provider for only the initial CMR is reported. The qualified provider must be reported as one of the following:

Physician, Registered Nurse, Licensed Practical Nurse, Nurse Practitioner, Physician's Assistant, Local Pharmacist, LTC Consultant Pharmacist, Plan Sponsor Pharmacist, Plan Benefit Manager (PBM) Pharmacist, MTM Vendor Local Pharmacist, MTM Vendor In-house Pharmacist, Hospital Pharmacist, Pharmacist □ Other, Supervised Pharmacy Intern, or Other. Required if received annual CMR.

",Update,Changes consistent with approved 2019 Part D TS & RR.,None

Part C: Grievances,,,,

RSC 5. Organization data passes data integrity checks listed below:,"RSC 5.

Organization data passes data integrity checks listed below: The number of expected counts (e.g., number of members, claims, grievances, procedures) are verified; ranges of data fields are verified; all calculations (e.g., derived data fields) are verified; missing data has been properly addressed; reporting output matches corresponding source documents (e.g., programming code, saved queries, analysis plans); version control of reported data elements is

appropriately applied; QA checks/thresholds are applied to detect outlier or

erroneous data prior to data submission",Update,Changes consistent with approved 2019 Part C TS & RR.,None

RSC-5.a: Total grievances in Data Element B does not exceed Data Element A.,RSC-

5.a: Total grievances in Data Element B does not exceed Data Element

B.,Update,Changes consistent with approved 2019 Part C TS & RR.,None

RSC-5.b: Includes total grievances in which timely notification was given (Data

Element B). ,RSC-5.b:Total grievances in which timely notification was given is Data Element D does not exceed Data Element B.,Update,Changes consistent with approved 2019 Part C TS & RR.,None

"RSC 6. The number of expected counts (e.g., number of members, claims, grievances, procedures) are verified; ranges of data fields are verified; all calculations (e.g., derived data fields) are verified; missing data has been properly addressed; reporting output matches corresponding source documents (e.g., programming code, saved queries, analysis plans); version control of reported data elements is appropriately applied; QA checks/thresholds are applied to detect outlier or erroneous data prior to data submission. ","RSC 6. Organization accurately calculates the total number of grievances, including the following criteria:","Changes consistent with approved 2019 Part C TS & RR., Part C: OD/RD , , , ,

"2.d RSC 4 Terms used are properly defined per CMS regulations, guidance and Reporting Requirements Technical Specifications.

1. Organization properly defines the term "Organization Determinations" in accordance with 42 C.F.R. Part 422, Subpart M, and the Parts C & D Enrollee Grievances, Organization/Coverage Determinations and Appeals Manual. This includes applying all relevant guidance properly when performing its calculations and categorizations.

2. Organization properly defines the term "Reconsideration" in accordance with 42 C.F.R. Part 422, Subpart M, and the the Parts C & D Enrollee Grievances, Organization/Coverage Determinations and Appeals Manual. This includes applying all relevant guidance properly when performing its calculations and categorizations.

","2.d RSC 4 Terms used are properly defined per CMS regulations, guidance and Reporting Requirements Technical Specifications.

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Organization properly defines the term "Reconsideration" in accordance with 42 C.F.R. Part 422, Subpart M, and the the Parts C & D Enrollee Grievances, Organization/Coverage Determinations and Appeals Manual. This includes applying all relevant guidance properly when performing its calculations and categorizations.

","Update,Changes consistent with approved 2019 Part C TS & RR.,None

RSC 5 Organization data passes data integrity checks listed below: ","RSC 5 Organization data passes data integrity checks listed below: The number of expected counts (e.g., number of members, claims, grievances, procedures) are verified; ranges of data fields are verified; all calculations (e.g., derived data fields) are verified; missing data have been properly addressed; reporting output matches corresponding source documents (e.g., programming code, saved queries, analysis plans); version control of reported data elements is appropriately applied; QA checks/thresholds are applied to detect outlier or erroneous data prior to data submission. ","Update,Changes consistent with approved 2019 Part C TS & RR.,None

"RSC 6. The number of expected counts (e.g., number of members, claims, grievances, procedures) are verified; ranges of data fields are verified; all calculations (e.g., derived data fields) are verified; missing data have been properly addressed; reporting output matches corresponding source documents (e.g., programming code, saved queries, analysis plans); version control of reported data elements is appropriately applied; QA checks/thresholds are applied to detect outlier or erroneous data prior to data submission. ","RSC 6. Organization accurately calculates the total number of organization determinations, including the following criteria:","Update,Changes consistent with approved 2019 Part C TS & RR.,None

"RSC-6.e: Includes organization determinations that are filed directly with the









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