Medical Necessity Guideline

Medical Necessity Guideline (MNG) Title: Medicare Part B Step Therapy		
MNG #: 040	☒**SCO** ☒**One Care** ☒ **MAPD-MA Medicare Preferred** ☒ **MAPD-MA Medicare Value** ☒ **MAPD-RI Medicare Preferred** ☒ **MAPD-RI Medicare Value** ☒ **DSNP-RI Medicare Maximum**	**Prior Authorization Needed?** ☒**Yes** ☐**No**
Clinical: ☒	**Operational:** ☐	**Informational:** ☐
Medicare Benefit: ☒**Yes** ☐**No**	**Approval Date:** 08/05/2020;	**Effective Date:** 12/18/2020;
Last Revised Date: 1/27/2021; 2/4/2021; 10/14/202; 01/06/2022;	**Next Annual Review Date:** 10/13/2021; 10/14/2022; 01/06/2023;	**Retire Date:**

OVERVIEW:

This Commonwealth Care Alliance (CCA) Medical Benefit Medicare Part B Step Therapy Medical Necessity Guideline (MNG) is for informational purposes only and does not constitute or replace medical advice. Physicians, hospitals and other providers are expected to care for their patients in such a way that they can use or administer drugs/biologicals in the most effective and clinically appropriate manner. Treating physicians and health care providers are solely responsible for making anydecisions about medical care.

Each benefit plan contains its own provisions for coverage, limitations and exclusions as stated in the member's Evidence of Coverage (EOC). If there is a discrepancy between this policy and the member's EOC, the member's EOC provision(s) will govern.

In the event of a conflict between this policy and Medicare National Coverage Determinations (NCD) or Local Coverage Determinations (LCD); the Medicare NCD/LCD will be applied.

Each class of medical benefit drugs covered under Medicare Part B referenced below includes preferred drugs(s)/product(s). Step therapy prior authorization for a non-preferred drug/product will generally require history of use of a preferred drug/product within the same medical benefit injectable class along with additional criteria. The medical benefit injectables that include non- preferred drug(s)/product(s) are subject to prior authorization, and preferred drug(s)/product(s), can be found below.

This Medical Benefit Part B Step Therapy Policy is applicable to CCA's One Care(Medicare-Medicaid) plan, Senior Care Options (SCO) duals plan, MA Medicare Preferred plan, MA Medicare Value plan, RI Medicare Preferred plan, RI Medicare Value plan, and RI Medicare Maximum duals plan.

Experimental and investigational procedures, items, and medications are not covered by CCA as outlined in Experimental and Investigational Drug MNG.

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DECISION GUIDELINES:

This CCA policy supplements Medicare Part B NCD, LCD, InterQual, and CCA drug/class-specific MNGs for determining coverage under Medicare Part B medical benefits. This policy implements a prior authorization or Step Therapy requirement for prescriptions or administrations of medical benefit drugs only.

A member cannot and will not be required under this policy to change a current drug/product

> For the purposes of this policy, a current drug/product means the member has a paid claim or clear clinical documentation (non-sample) for the drug/product within the past 365 days (claims look-back period).

DESCRIPTION OF SERVICES:

Specific classes of medical benefit drugs covered under Medicare Part B will include non-preferred therapies that require prior authorization. Prior authorization for a non-preferred therapy will generally require history of use of a preferred therapy within the same medical benefit injectable class, among other criteria. If a provider administers a non-preferred therapy without obtaining prior authorization, CCA may deny the claim for the non-preferred therapy.

CCA MNGs for specific Part B drugs include:

Select Biologic Agents MNG
Hyperlink to HA Knee MNG

MEDICAL THERAPEUTIC DRUG CLASSES

There are specific classes of medical benefit drugs covered under Medicare Part B that will include preferred and non-preferred drugs or products. The drugs or products may be biosimilars or products with multiple manufacturers. There are an increasing number of FDA approved biosimilar drugs/products available in marketplace. A biosimilar is a biological product approved based on data demonstrating that it is highly similar to an FDA- approved biological product, known as the reference product, and that there are no clinically significant differences between the biosimilar product and the reference product. Biosimilars produce equivalent therapeutic results and are lower cost than brand name alternatives. This policy only applies to biological agents being used for FDA approved indications. In instances where the preferred drug is unavailable, the non-preferred drug(s) may be requested and approved by CCA. Availability is defined by CCA as a regional or nationwide shortage of a drug that is not specific to a single distributor or provider.

This policy applies step therapy for the following drugs:

Class	Drug Name
Biologics	Bevacizumab
	Epoetin alfa
	Filgrastim
	Infliximab
	Pegfilgrastim
	Rituximab
	Trastuzumab

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Hyaluronic Acid Derivatives	Durolane
	Euflexxa
	Gelsyn-3
	Supartz
	Gel One
	GenVisc 850
	Hyalgan
	Hymovis
	Monovisc
	Orthovisc
	Synojoynt
	Synvisc
	Synvisc One
	Triluron

Preferred Drug List: Click Here

STEP THERAPY (NEW STARTS ONLY) DRUG CRITERIA

BEVACIZUMAB

PREFERRED DRUG(S): Mvasi (bevacizumab-awwb), Zirabev (bevacizumab-bvzr)

- Non-preferred drug(s): Avastin® (bevacizumab)
- Non-preferred step therapy criteria:
    - Avastin® (bevacizumab) may be used when the criteria listed under one of the following Sections I, II, III are satisfied:

I. All of the following:
   A. History of use of Mvasi (bevacizumab-awwb) and Zirabev (bevacizumab-bvzr) resulting in minimal clinical response **AND**
   B. Physician attestation that in their clinical opinion the clinical response would be expected to be superior with Avastin® (bevacizumab)

OR

II. All of the following:
   A. History of intolerance or adverse event to Mvasi (bevacizumab-awwb) and Zirabev (bevacizumab-bvzr) **AND**
   B. Physician attestation that in their clinical opinion the same intolerance or adverse event would not be expected to occur with Avastin® (bevacizumab)

AND

   C. For members who are unable to tolerate Mvasi (bevacizumab-awwb) and Zirabev (bevacizumab-bvzr) or in the rare instance that they are contraindicated for a member, documentation is required and must indicate the reason why the member cannot use Mvasi (bevacizumab-awwb) and Zirabev (bevacizumab-bvzr).

OR

III. Use of requested non-preferred drug(s) within the past 365 days.

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Code	Description *(mg = milligram)
J9035	Injection, Avastin® (bevacizumab), 10mg
Q5107	Injection, Mvasi (bevacizumab-awwb), 10mg
Q5118	Injection, Zirabev (bevacizumab-bvzr), 10mg

EPOETIN ALFA

PREFERRED DRUG(S): Retacrit (epoetin alfa-epbx)

- Non-Preferred Drug(s): Epogen®(epoetin alfa), Procrit®(epoetin alfa)
- Non-Preferred Step Therapy criteria:
    - Epogen®(epoetin alfa), Procrit®(epoetin alfa) may be used when the criteria listed under one of the following sections I, II, III are satisfied:

I. All of the following:
   A. History of use of Retacrit (epoetin alfa-epbx) resulting in minimal clinical response **AND**
   B. Physician attestation that in their clinical opinion the clinical response would be expected to be superior with Epogen®(epoetin alfa), Procrit®(epoetin alfa)

OR

II. All of the following:
   A. History of intolerance or adverse event to Retacrit (epoetin alfa-epbx) **AND**
   B. Physician attestation that in their clinical opinion the same intolerance or adverse event would not be expected to occur with Epogen®(epoetin alfa), Procrit®(epoetin alfa) **AND**
   C. For members who are unable to tolerate Retacrit (epoetin alfa-epbx) or in the rare instance that Retacrit (epoetin alfa-epbx) is contraindicated for a member, documentation is required and must clearly indicate the reason why the member cannot use Retacrit (epoetin alfa-epbx)

OR

III. Use of requested non-preferred drug(s) within the past 365 days.

HCPCS CODES

Code	Description
J0885	Injection, Epogen®/Procrit® (epoetin alfa), 1000 units
Q5106	Injection, Retacrit (epoetin alfa-epbx), 1000 units

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Hyaluronic Acid (HA) Derivatives

PREFERRED DRUG(S): Durolane, Euflexxa, Gelsyn-3, Supartz

- Non-preferred drug(s): Gel One, GenVisc 850, Hyalgan, Hymovis, Monovisc, Orthovisc, Synojoynt, Synvisc, Synvisc One, Trivisc, Triluron, and VISCO-3
- Non-preferred step therapy criteria: Non-preferred HA derivatives may be used when the criteria under one of the following sections I, II, III are satisfied:

I. All of the following:
   A. History of a completed trial of Durolane, Euflexxa, Gelsyn-3, or Supartz resulting in minimal clinical response **AND**
   B. Physician attestation that in their clinical opinion the clinical response would be expected to be superior with the non-preferred drugs

OR

II. All the following:
   A. History of intolerance or adverse event to Durolane, Euflexxa, Gelsyn-3, or Supartz

AND

   B. Physician attestation that in their clinical opinion the same intolerance or adverse event would not be expected to occur with Gel One, GenVisc 850, Hyalgan, Hymovis, Monovisc, Orthovisc, Synojoynt, Synvisc, Synvisc One, and Triluron

AND

   C. For members who are unable to tolerate Durolane, Euflexxa, Gelsyn-3, or Supartz or in the instance that the preferred products above are contraindicated for a member, documentation is required and must indicate the reason why the member cannot take one of the above preferred products. The rationale must be clearly documented.

OR

III. Use of requested non-preferred drug(s) within the past 365 days.

HCPCS CODES:

Code	Description *(mg = milligram)
J7318	Hyaluronan or derivative, Durolane, for intra-articular injection, 1 mg
J7320	Hyaluronan or derivative, Genvsic 850, for intra-articular injection, 1 mg
J7321	Hyaluronan or derivative, Hyalgan or Supartz, for intra-articular
J7322	Hyaluronan or derivative, Hymovis, for intra-articular injection, 1 mg

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J7323	Hyaluronan or derivative, Euflexxa, for intra-articular injection, per dose
J7324	Hyaluronan or derivative, Orthovisc, for intra-articular injection, per dose
J7325	Hyaluronan or derivative, Synvisc or Synvisc-One, for intra-articular injection, 1 mg
J7326	Hyaluronan or derivative, Gel-One, for intra-articular injection, per dose
J7327	Hyaluronan or derivative, Monovisc, for intra-articular injection, per dose
J7328	Hyaluronan or derivative, GELSYN-3, for intra-articular injection, 0.1 mg
J7329	Hyaluronan or derivative, Trivisc, for intra-articular injection, 1 mg
J7331	Hyaluronan or derivative, Synojoynt, for intra-articular injection, 1 mg
J7332	Hyaluronan or derivative, Triluron, for intra-articular injection, 1 mg
J7333	Hyaluronan or derivative, VISCO-3, for intra-articular injection, 1 mg

INFLIXIMAB

PREFERRED DRUG(S): Renflexis (infliximab-abda)

- Non-preferred drug(s): Remicade® (infliximab), Inflectra (infliximab-dyyb), Avsola (infliximab-axxq)
- Non-preferred step therapy criteria:
  - Remicade® (infliximab), Inflectra (infliximab-dyyb), Avsola (infliximab-axxq) may be used when the criteria listed under one of the following sectionsI, II, III are satisfied:

I. All of the following:

A. Trial of at least 14 weeks of Renflexis (infliximab-abda) resulting in minimal clinical response to therapy and residual disease activity **AND**

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B. Physician attestation that in their clinical opinion the clinical response would be expected to be superior with Remicade® (infliximab), Inflectra (infliximab-dyyb), Avsola (infliximab-axxq) rather than with Renflexis (infliximab-abda)

OR

II. All of the following:
   A. History of intolerance or adverse event to Renflexis (infliximab-abda) **AND**
   B. Physician attestation that in their clinical opinion the same intolerance or adverse event would not be expected to occur with Remicade® (infliximab), Inflectra (infliximab-dyyb), Avsola (infliximab-axxq **AND**
   C. For members who are unable to tolerate Renflexis (infliximab-abda) or in the instance that the preferred product(s) above are contraindicated for a member, documentation is required and must clearly indicate the reason why the member cannot take one of the above preferred product(s).

OR

III. Use of requested non-preferred drug(s) within the past 365 days.

HCPCS CODES:

Code	Description *(mg = milligram)
J1745	Injection, infliximab (Remicade®), 10mg
Q5103	Injection, infliximab-dyyb, biosimilar (Inflectra), 10mg
Q5104	Injection, infliximab-abda, biosimilar (Renflexis), 10mg
Q5121	Injection, infliximab-axxq, biosimilar (Avsola),10mg

FILGRASTIM: SHORT-ACTING

PREFERRED DRUG(S): Nivestym (filgrastim-aafi), Zarxio (filgrastim-sndz)

- Non-preferred drug(s): Granix (filgrastim-tbo), Neupogen® (filgrastim)
- Non-preferred step therapy criteria:
  - Granix (filgrastim-tbo), Neupogen® (filgrastim) may be used when the criteria listed under one of the following Sections I, II, and III are satisfied:

I. Both of the following:
   A. History of use of Nivestym (filgrastim-aafi) and Zarxio (filgrastim-sndz) resulting in minimal clinical response to therapy **AND**
   B. Physician attestation that in their clinical opinion the clinical response would be expected to be superior with Granix (filgrastim-tbo), Neupogen® (filgrastim)

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OR

II. All of the following:

A. History of Nivestym (filgrastim-aafi) and Zarxio (filgrastim-sndz) intolerance or adverse event to Nivestym (filgrastim-aafi) and Zarxio (filgrastim-sndz) **AND**

B. Physician attestation that in their clinical opinion the same intolerance or adverse event would not be expected to occur with Granix (filgrastim-tbo), Neupogen® (filgrastim) **AND**

C. For members who are unable to tolerate Nivestym (filgrastim-aafi) and Zarxio (filgrastim-sndz) or in the rare instance that Nivestym (filgrastim-aafi) and Zarxio (filgrastim-sndz) are contraindicated for a member, documentation is required and must clearly indicate the reason why the member cannot use Nivestym (filgrastim-aafi) and Zarxio (filgrastim-sndz)

OR

III. Use of requested non-preferred drug(s) within the past 365 days.

HCPCS CODES

Code	Description (*mcg = microgram)
J1442	Injection, filgrastim (G-CSF), (Neupogen®), 1 mcg
J1447	Injection, filgrastim-tbo, (Granix), 1 mcg
Q5101	Injection, filgrastim-sndz, (Zarxio), 1 mcg
Q5110	Injection, filgrastim-aafi, (Nivestym), 1 mcg

PEGFILGRASTIM: LONG ACTING

PREFFERRED DRUGS: Fulphilia (pegfilgrastim-jmdb), Ziextenzo (pegfilgrastim-bmez)

- Non-preferred drug(s): Neulasta® (pegfilgrastim), Udenyca (pegfilgrastim-cbqv), Nyvepria (pegfilgrastim-apgf)
- Non-preferred step therapy criteria:
  - Neulasta® (pegfilgrastim), Udenyca (pegfilgrastim-cbqv), Nyvepria (pegfilgrastim-apgf) may be used when the criteria listed under one of the following Sections I, II, III are satisfied:

IV. All of the following:

A. History of use of Fulphilia (pegfilgrastim-jmdb) and Ziextenzo (pegfilgrastim-bmez) resulting in minimal clinical response **AND**

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B. Physician attestation that in their clinical opinion the clinical response would be expected to be superior with Neulasta® (pegfilgrastim), Udenyca (pegfilgrastim-cbqv), Nyvepria (pegfilgrastim-apgf)

OR

V. All the following:

A. History of intolerance or adverse event to Fulphilia (pegfilgrastim-jmdb) and Ziextenzo (pegfilgrastim-bmez) **AND**

B. Physician attestation that in their clinical opinion the same intolerance or adverse event would not be expected to occur with Neulasta® (pegfilgrastim), Udenyca (pegfilgrastim-cbqv), Nyvepria (pegfilgrastim-apgf) **AND**

C. For members who are unable to tolerate Fulphilia (pegfilgrastim-jmdb) and Ziextenzo (pegfilgrastim-bmez) or in the rare instance that Fulphila (pegfilgrastim-jmdb) and Ziextenzo (pegfilgrastim-bmez) are contraindicated for a member, documentation is required and must clearly indicate the reason why the member cannot use Fulphilia (pegfilgrastim-jmdb) and Ziextenzo (pegfilgrastim-bmez)

OR

VI. Use of requested non-preferred drug(s) within the past 365 days.

HCPCS CODES

Code	Description *(mg = milligram)
J2505	Injection, pegfilgrastim, (Neulasta) 6 mg
Q5108	Injection, pegfilgrastim-jmdb, (Fulphila), 0.5 mg
Q5111	Injection, pegfilgrastim-cbqv, (Udenyca), 0.5 mg
Q5120	Injection, pegfilgrastim-bmez, (Ziextenzo), 0.5mg
Q5122	Injection, pegfilgrastim-apgf, (Nyvepria), 0.5mg

TRASTUZUMAB

PREFERRED DRUG(S): Ogivri (trastuzumab-dkst)

- Non-Preferred Drug(s): Herceptin® (trastuzumab), Herzuma (trastuzumab-pkrb), Kanjinti (trastuzumab-anns),Ontruzant (trastuzumab-dttb), Trazimera (rastuzumab-qyyp)
- Non-Preferred Step Therapy criteria:

  Herceptin® (trastuzumab), Herzuma (trastuzumab-pkrb), Kanjinti (trastuzumab-anns), Ontruzant (trastuzumab-dttb), Trazimera (rastuzumab-qyyp) may be used when the criteria listed under one of the following Sections I, II, III are satisfied:

I. All of the following:

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A. History of use of Ogivri (trastuzumab-dkst) resulting in minimal clinical response **AND**
B. Physician attestation that in their clinical opinion the clinical response would be expected to be superior with Herceptin® (trastuzumab), Herzuma (trastuzumab-pkrb), Kanjinti (trastuzumab-anns), Ontruzant (trastuzumab-dttb), and Trazimera (rastuzumab-qyyp)

OR

II. All of the following:
A. History of intolerance or adverse event to Ogivri (trastuzumab-dkst) **AND**
B. Physician attestation that in their clinical opinion the same intolerance or adverse event would not be expected to occur with Herceptin® (trastuzumab), Herzuma (trastuzumab-pkrb), Kanjinti (trastuzumab-anns), Ontruzant (trastuzumab-dttb), Trazimera (rastuzumab-qyyp) **AND**
C. For members who are unable to tolerate Ogivri (trastuzumab-dkst) or in the rare instance that Ogivri (trastuzumab-dkst) is contraindicated for a member, documentation is required and must clearly indicate the reason why the member cannot use Ogivri (trastuzumab-dkst)

OR

III. Use of requested non-preferred drug(s) within the past 365 days.

HCPCS CODES

Code	Description *(mg = milligrams)
J9355	Injection, Herceptin® (trastuzumab),10mg
Q5112	Injection, Ontruzant (trastuzumab-dttb), 10mg
Q5113	Injection, Herzuma (trastuzumab-pkrb), 10mg
Q5114	Injection, Ogivri (trastuzumab-dkst), 10mg
Q5116	Injection, Trazimera (rastuzumab-qyyp), 10mg
Q5117	Injection, Kanjinti (trastuzumab-anns), 10mg

RITUXIMAB

PREFERRED DRUG: Truxima (rituximab-abbs), Ruxience (rituximab-pvvr)

- Non-Preferred Drug(s): Rituxan®(rituximab), Riabni (rituximab-arrx)
- Non-Preferred Step Therapy criteria:
  - Rituxan®(rituximab), Riabni (rituximab-arrx) may be used when the criteria listed under one of the following sections I, II, III are satisfied:

I. All of the following:
A. History of use of Truxima (rituximab-abbs) and Ruxience (rituximab-pvvr) resulting in minimal clinical response **AND**
B. Physician attestation that in their clinical opinion the clinical response would be expected to be superior with Rituxan®(rituximab), Riabni (rituximab-arrx)

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OR

II. All of the following:
   A. History of intolerance or adverse event to Truxima (rituximab-abbs) and Ruxience (rituximab-pvvr) **AND**
   B. Physician attestation that in their clinical opinion the same intolerance or adverse event would not be expected to occur with Rituxan®(rituximab), Riabni (rituximab-arrx) **AND**
   C. For members who are unable to tolerate Truxima (rituximab-abbs) and Ruxience (rituximab-pvvr) or in the rare instance that Truxima (rituximab-abbs) and Ruxience (rituximab-pvvr) are contraindicated for a member, documentation is required and must clearly indicate the reason why the member cannot use Truxima (rituximab-abbs) and Ruxience (rituximab-pvvr)

OR

III. Use of requested non-preferred drug(s) within the past 365 days.

HCPCS CODES

Code	Description *(mg = milligrams)
J9312	Injection, Rituxan® (rituximab), 10mg
Q5115	Injection, Truxima (rituximab-abbs), 10mg
Q5119	Injection, Ruxience (rituximab-pvvr), 10mg
Q5123	Injection, Riabni (rituximab-arrx), 10mg

LIMITATIONS/EXCLUSIONS:
Senior Care Options (Massachusetts Health Only-MHO) members.

Disclaimer:
This Medical Necessity Guideline is not a rigid rule. As with all of CCA's criteria, the fact that a member does not meet these criteria does not, in and of itself, indicate that no coverage can be issued for these services. Providers are advised, however, that if they request services for any member who they know does not meet our criteria, the request should be accompanied by clear and convincing documentation of medical necessity. The preferred type of documentation is the letter of medical necessity, indicating that a request should be covered either because there is supporting science indicating medical necessity (supporting literature (full text preferred) should be attached to the request), or describing the member's unique clinical circumstances, and describing why this service or supply will be more effective and/or less costly than another service which would otherwise be covered. Note that both supporting scientific evidence and a description of the member's unique clinical circumstances will generally be required.

RELATED REFERENCES:

1. https://www.cms.gov/Medicare/Health-

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Plans/HealthPlansGenInfo/Downloads/MA_Step_Therapy_HPMS_Memo_8_7_2018.pdf
2. https://www.federalregister.gov/documents/2019/05/23/2019-10521/modernizing-part-d-and-medicare-advantage-to-lower-drug-prices-and-reduce-out-of-pocket-expenses
3. https://www.cms.gov/newsroom/fact-sheets/medicare-advantage-prior-authorization-and-step-therapy-part-b-drugs
4. https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update
5. https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS
6. https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/biosimilars

ATTACHMENTS:

EXHIBIT A: Part B Step Therapy Preferred Drug List	Part B Step Therapy Preferred Drug List

REVISION LOG:

REVISION DATE	DESCRIPTION
9/23/2021	Nyvepria and Riabni added to policy (new biosimilars) Changed Inflectra from preferred to non-preferred Changed Ziextenzo and Ruxience from non-preferred to preferred Added epoetin alfa (Epogen/Procrit) and Retacrit to policy
12/27/2021	Added language related to drug shortages

APPROVALS:

Derek McFerran	Director, Pharmacy Program
CCA Senior Clinical Lead [Print]	**Title [Print]**
Derek McFerran	08/05/2020
Signature	**Date**
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CCA Senior Operational Lead [Print]	**Title [Print]**
Signature	**Date**
Lori Tishler	Sr. Vice President, Medical Services
CCA CMO or Designee [Print]	**Title [Print]**

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Signature

08/05/2020

Date

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