Clinical Policy: Atezolizumab (Tecentriq)

Reference Number: LA.PHAR.235
Effective Date: 04.28.21
Last Review Date: ~~01.21~~06.15.23
Line of Business: Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Please note: This policy is for medical benefit

Description

Atezolizumab (Tecentriq®) is a programmed death-ligand 1 (PD-L1) blocking antibody.

FDA Approved Indication(s)

Tecentriq is indicated:

~~• Urothelial carcinoma (UC)~~
- ~~For the treatment of adult patients with locally advanced or metastatic urothelial carcinoma who:~~
  - ~~are not eligible for cisplatin-containing chemotherapy and whose tumors express PD-L1 (PD-L1 stained tumor-infiltrating immune cells [IC] covering ≥ 5% of the tumor area), as determined by an FDA-approved test.~~
  - ~~are not eligible for any platinum-containing chemotherapy regardless of PD-L1 status.~~
  - ~~have disease progression during or following any platinum-containing chemotherapy, or within 12 months of neoadjuvant or adjuvant chemotherapy.~~

~~*This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).*~~

- **Non-small cell lung cancer (NSCLC)**
  - As adjuvant treatment following resection and platinum-based chemotherapy for adult patients with stage II to IIIA NSCLC whose tumors have PD-L1 expression on ≥ 1% of tumor cells, as determined by an FDA-approved test
  - For the first-line treatment of adult patients with metastatic NSCLC whose tumors have high PD-L1 expression (PD-L1 stained ≥ 50% of tumor cells [TC ≥ 50%] or PD-L1 stained tumor-infiltrating immune cells [IC] covering ≥ 10% of the tumor area [IC ≥ 10%]), as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations.
  - In combination with bevacizumab, paclitaxel, and carboplatin, for the first-line treatment of adult patients with metastatic non-squamous NSCLC with no EGFR or ALK genomic tumor aberrations.
  - In combination with paclitaxel protein-bound and carboplatin for the first-line treatment of adult patients with metastatic non-squamous NSCLC with no EGFR or ALK genomic tumor aberrations.

- For the treatment of adult patients with metastatic NSCLC who have disease progression during or following platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for NSCLC harboring these aberrations prior to receiving Tecentriq.

- ~~**Triple-negative breast cancer (TNBC)**~~
  - ~~**In combination with paclitaxel protein-bound for the treatment of adult patients with unresectable locally advanced or metastatic TNBC whose tumors express PD-L1 (PD-L1 stained tumor-infiltrating immune cells [IC] of any intensity covering ≥ 1% of the tumor area), as determined by an FDA-approved test.**~~
    ~~***This indication is approved under accelerated approval based on progression free survival. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).***~~
- **Small cell lung cancer (SCLC)**
  - In combination with carboplatin and etoposide, for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC).
- **Heptatocellular carcinoma (HCC)**
  - In combination with bevacizumab for the treatment of patients with unresectable or metastatic HCC who have not received prior systemic therapy.
- **Melanoma**
  - ~~o~~ In combination with cobimetinib and vemurafenib for the treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma.
  - o
- ~~•~~ **Alveolar soft part sarcoma (ASPS)**
- ~~•~~
  - ~~o~~ For the treatment of adult and pediatric patients 2 years of age and older with unresectable or metastatic ASPS.

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Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Louisiana Healthcare Connections® that Tecentriq is **medically necessary** when the following criteria are met:

~~I.~~ **Initial Approval Criteria**
~~**Urothelial Carcinoma (must meet all):**~~
~~Diagnosis of UC;~~
~~Prescribed by or in consultation with an oncologist;~~
~~Age ≥ 18 years;~~
~~One of the following (a, b, or c):~~
~~Member is ineligible for cisplatin-containing chemotherapy, and the tumor expresses PD-L1;~~
~~Member is ineligible for any platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin) regardless of PD-L1 status;~~
~~Disease has progressed during or following platinum-containing chemotherapy;~~
~~Request meets one of the following (a or b):*~~

~~Dose does not exceed 1,680 mg every 4 weeks;~~
~~Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence)*.~~

~~XIII.~~I.

A. Non-Small Cell Lung Cancer (must meet all)**:**

1. Diagnosis of ~~recurrent, advanced, or metastatic~~ NSCLC;
2. Prescribed by or in consultation with an oncologist;
3. ~~3.~~ Age ≥ 18 years;
3.
4. ~~4.~~ Member meets one of the following (a, b, or c):
   - ~~a.~~ ~~a.~~ For stage II to IIIA NSCLC, prescribed as a single agent and meets one of the
   - ~~b.~~a. following (i or ii):
     i. ~~i.~~ Member has had previous resection;
     ii. ~~ii.~~ Member has all the following (1, 2 and 3):
1. ~~1)~~ High-risk stage IIA NSCLC (*see Appendix D*);
2. ~~2)~~ PD-L1 expression ≥ 1%;
3. ~~3)~~ Previously received platinum-containing chemotherapy (*see Appendix B*);
   - ~~c.~~ ~~b.~~ For member with both a negative or unknown EGFR or ALK mutation status
   - ~~d.~~b. AND recurrent, advanced, or metastatic NSCLC: Member meets one of the following (i, ii, iii, or iv):
     ~~i.~~ Request is for use as a single agent as first-line therapy for tumors that have high PD-L1 expression (PD-L1 ≥ 50% [TC ≥ 50%] or tumor-infiltrating IC covering ≥ 10% of the tumor area [IC ≥ 10%]);
     i.
     ~~ii.~~ ~~ii.~~ Disease is non-squamous, and Tecentriq is prescribed in combination with
     ~~iii.~~ii. one of the following (1 or 2):
       ~~1. 1)~~ Bevacizumab, paclitaxel, and carboplatin;
       1.
       ~~2. 2)~~ Paclitaxel protein-bound (Abraxane®) and carboplatin;

~~iii. Member has previously received platinum-containing chemotherapy (see Appendix B);~~

2.
iii. Member has previously received platinum-containing chemotherapy (*see Appendix B*);
~~iv.~~ If no prior progression on a PD-1/PD-L1 inhibitor (i.e., Tecentriq as well as
~~iii.~~ nivolumab, pembrolizumab, durvalumab), request is for single agent as
iv. subsequent therapy;

   - ~~e.~~ ~~c.~~ For member with a positive EGFR or ALK mutation status AND recurrent,
   - ~~f.~~ advanced, or metastatic NSCLC: Member has a history of disease progression

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~~g.~~ during or following an NCCN-recommended therapy for the specific mutation
~~h.~~c. (*see Appendix B*);

5. ~~5.~~ Request meets one of the following (a or b):*
   a. ~~a.~~ Dose does not exceed 1,680 mg every 4 weeks;
   ~~b.~~ ~~b.~~ Dose is supported by practice guidelines or peer-reviewed literature for the
   ~~c.~~b. relevant off-label use (prescriber must submit supporting evidence).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

B. Small Cell Lung Cancer (must meet all)**:**

1. Diagnosis of extensive-stage SCLC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed in combination with carboplatin and etoposide;
5. Request meets one of the following (a or b):*
   a. Dose does not exceed 1,680 mg every 4 weeks;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

C. Hepatocellular Carcinoma (must meet all)**:**

1. Diagnosis of HCC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed in combination with bevacizumab as first-line systemic therapy;
~~4.~~5.Confirmation of Child-Pugh class A status;
~~5.~~6.Request meets one of the following (a or b):*
   a. Dose does not exceed 1,680 mg every 4 weeks;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

D. Melanoma (must meet all)**:**

1. Diagnosis of melanoma with BRAF V600 mutation;
2. Disease is unresectable or metastatic;
3. Prescribed by or in consultation with an oncologist;
4. Age ≥ 18 years;
5. Prescribed in combination with cobimetinib and vemurafenib;
6. Request meets one of the following (a or b):*

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a. Dose does not exceed 1,680 mg every 4 weeks~~840 mg every 2 weeks;~~
b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

E. Alveolar Soft Part Sarcoma (must meet all)**:**

~~7.~~1.~~1.~~ Diagnosis of ASPS;
~~2.~~ Disease is unresectable or metastatic;
2.
~~3.~~ Prescribed by or in consultation with an oncologist;
~~8.~~3.
~~4.~~ Age ≥ 2 years;
4.
5. ~~5.~~ Request meets one of the following (a or b):*
   a. ~~a.~~ Dose does not exceed one of the following (i or ii):
      i. ~~i.~~ Adults: 1,680 mg every 4 weeks;
      ii. ~~ii.~~ Pediatrics: 15 mg/kg (up to a maximum of 1,200 mg) every 3 weeks;
   ~~b.~~ Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-
   b. ~~-~~label use (*prescriber must submit supporting evidence*).

** Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

F. ~~F.~~ Peritoneal Mesothelioma (off-label) (must meet all)**:**

1. ~~1.~~ Diagnosis of peritoneal mesothelioma;
2. ~~2.~~ Prescribed by or in consultation with an oncologist;
3. ~~3.~~ Age ≥ 18 years;
4. ~~4.~~ Prescribed in combination with bevacizumab as subsequent systemic therapy;
5. ~~5.~~ Dose is within FDA maximum limit for any FDA-approved indication or is supported
   ~~-~~by practice guidelines or peer-reviewed literature for the relevant off-label use
   ~~-~~(*prescriber must submit supporting evidence*).*
6.

*** Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

G. Urothelial Carcinoma (off-label) (must meet all):

1. Diagnosis of urothelial carcinoma (UC);
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. One of the following (a or b):
   a. Member is ineligible for cisplatin-containing chemotherapy, and the tumor expresses PD-L1;

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b. Member is ineligible for any platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin) regardless of PD-L1 status;

6. Prescribed as a single agent;
7. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*). **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

H. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255~~Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace and CPLA.PMN.53 for Medicaid~~.

~~1.~~2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: LA.PMN.53 for Medicaid.

II Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via Louisiana Healthcare Connections benefit, or documentation supports that member is currently receiving Tecentriq for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b~~, b, or c~~):*
   a. New dose does not exceed one of the following (i or ii):
      i. ~~i.~~ For pediatric ASPS: 15 mg/kg (up to a maximum of 1,200 mg) every 3 weeks; ~~ii.~~
      ~~i.~~ii. All other indications: 1,680 mg every 4 weeks;
   b. ~~;~~New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence)*.

   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

~~1.~~ If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to~~Currently receiving medication via Lousiana Healthcare ConnectionsCentene benefit and documentation supports positive response to therapy.~~

~~2. Approval duration: Duration of request or 6 months (whichever is less); o~~ LA. PMN.255~~r~~

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~~3.~~2.If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: LA.PMN.53 for Medicaid.~~Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): LA.PMN.53 for Medicaid.~~

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III Diagnoses/Indications for which coverage is NOT authorized:

Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – LA.PMN.53 for Medicaid, or evidence of coverage documents.

A.

IV.

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Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ALK: anaplastic lymphoma kinase
ASPS: alveolar soft part sarcoma
EGFR: epidermal growth factor receptor
ES-SCLC: extensive-stage small cell lung cancer
FDA: Food and Drug Administration
HCC: hepatocellular carcinoma
IC: immune cells
NSCLC: non-small cell lung cancer
PD-L1: programmed death-ligand 1
SCLC: small cell lung cancer
TC: tumor cells
UC: urothelial carcinom

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
cisplatin-, oxaliplatin- (Eloxatin®) or carboplatin-containing chemotherapy	UC: Varies	Varies
cisplatin-, or carboplatin-containing chemotherapy	NSCLC: Varies	Varies
Xalkori® (crizotinib) Alecensa® (alectinib) Zykadia® (ceritinib)	NSCLC with ALK tumor aberration: Varies	Varies
Tarceva® (erlotinib) Gilotrif® (afatinib) Iressa® (gefitinib)	NSCLC with EGFR tumor aberration: Varies	Varies

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

None reported

Appendix D: General Information

• NSCLC examples of high-risk factors: may include poorly differentiated tumors (including lung neuroendocrine tumors [excluding well-differentiated neuroendocrine tumors]), vascular invasion, wedge resection, tumors > 4 cm, visceral pleural involvement, and unknown lymph node status. These factors independently may or may not be an indication and may be considered when determining treatment with adjuvant chemotherapy.

• SCLC consists of two stages: limited-stage and extensive-stage. Extensive-stage is defined as stage IV (T any, N any M 1a/b) or T3-4 due to multiple lung nodules that are too extensive or have tumor/nodal volume that is too large to be encompassed in a tolerable radiation plan.

• On December 2, 2022, following consultation with the FDA, Roche withdrew Tecentriq's use for any form of UC. The withdrawal was based on data from the IMVigor130 study, which tested Tecentriq with chemotherapy against chemotherapy alone and failed to meet the co-primary endpoint of overall survival. Patients given Tecentriq chemo combination lived a median of 16 months after treatment, compared with 13.4 months for those receiving just chemo, a difference that wasn't statistically significant.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
NSCLC	In the adjuvant setting: administer Tecentriq following resection and up to 4 cycles of platinum-based chemotherapy as 840 mg IV every 2 weeks, 1,200 mg IV every 3 weeks, or 1,680 mg IV every 4 weeks for up to 1 year In the metastatic setting: administer Tecentriq as 840 mg IV every 2 weeks, 1,200 mg IV every 3 weeks, or 1,680 mg IV every 4 weeks When administering with chemotherapy with or without bevacizumab, administer Tecentriq prior to chemotherapy and bevavizumab when given on the same day	1,680 mg/4 weeks
SCLC	840 mg IV every 2 weeks, 1,200 mg IV every 3 weeks, or 1,680 mg IV every 4 weeks. When administering with carboplatin and etoposide, administer Tecentriq prior to chemotherapy when given on the same day.	1,680 mg/4 weeks
HCC	840 mg IV every 2 weeks, 1,200 mg IV every 3 weeks, or 1,680 mg IV every 4 weeks. Administer Tecentriq prior to bevacizumab when given on the same day. Bevacizumab is administered at 15 mg/kg every 3 weeks.	1,680 mg/4 weeks

Indication	Dosing Regimen	Maximum Dose
Melanoma	Following completion of a 28 day cycle of cobimetinib and vemurafenib, administer Tecentriq 840 mg IV every 2 weeks, 1,200 mg every 3 weeks, or 1680 mg every 4 weeks with cobimetinib 60 mg PO QD (21 days on/7 days off) and vemurafenib 720 mg PO BID	1,680 mg/4 weeks
ASPS	Adults: 840 mg IV every 2 weeks, 1,200 mg IV every 3 weeks, or 1,680 mg IV every 4 weeks Pediatrics: 15 mg/kg (up to a maximum of 1,200 mg) every 3 weeks	Adults: 1,680 mg/4 weeks Pediatrics: 1,200 mg/3 weeks

VI. Product Availability

Single-dose vial: 840 mg/14 mL, 1,200 mg/20 mL

VII. References

1. Tecentriq Prescribing Information. South San Francisco, CA: Genentech, Inc.; December 2022. Available at: https://www.tecentriq.com. Accessed January 9, 2023.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: nccn.org. Accessed January 9, 2023.
3. National Comprehensive Cancer Network Guidelines. Non-Small Cell Lung Cancer Version 5.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed November 4, 2022.
4. National Comprehensive Cancer Network Guidelines. Hepatobiliary Cancers Version 3.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/hepatobiliary.pdf. Accessed November 4, 2022.
5. National Comprehensive Cancer Network Guidelines. Bladder Cancer Version 2.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/bladder.pdf. Accessed December 7, 2022.
6. National Comprehensive Cancer Network Guidelines. Malignant Peritoneal Mesothelioma Version 2.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/mpem.pdf. Accessed November 4, 2022.
7. National Comprehensive Cancer Network Guidelines. Melanoma: Cutaneous Version 3.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cutaneous_melanoma.pdf. Accessed November 4, 2022.

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~~20.~~ ~~8.~~ National Comprehensive Cancer Network Guidelines. Soft Tissue Sarcoma Version ~~21.~~ 2.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf. ~~8.~~ Accessed January 9, 2023.

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Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J9022	Injection, atezolizumab, 10 mg

Reviews, Revisions, and Approvals	Date	LDH Approval Date
Converted corporate to local policy	01.21	04.18.21
Removed breast cancer indication and added NSCLC stage II to IIIA treatment indication per updated label; added criterion for use as single-agent therapy for urothelial carcinoma per NCCN; added criterion for Child-Pugh class A status in HCC per NCCN; references reviewed and updated. Template changes applied to other diagnoses/indications and continued therapy section. Added criterion for malignant peritoneal mesothelioma per NCCN; adjusted dose to not exceed 1,680 mg every 4 weeks for melanoma per PI; section V updated per PI; revised commercial approval duration to the current standard for injectables of "6 months or to member's renewal date, whichever is longer"; references reviewed and updated. For urothelial carcinoma, removed FDA approved accelerated indication per updated PI and changed to off-label as still supported by NCCN; added ASPS indication per updated PI. Added blurb this policy is for medical benefit only.	06.15.23	

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing

this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. LHCC retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

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