JOHNS HOPKINS MEDICINE / JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Medical Management Drug Policies**	*Policy Number*	MMDP060
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	Subject **Tecentriq**	*Revision Date*	04/20/2022
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This document applies to the following Participating Organizations:

US Family Health Plan

Keywords: tecentriq

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I. POLICY

A. Tecentriq (atezolizumab) will require prior authorization for medical benefit coverage to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.

II. POLICY CRITERIA

A. Tecentriq may be approved for patients who meet the following:
   1. Urothelial Carcinoma - Bladder Cancer
      a. Documentation has been submitted showing Tecentriq will be used as first-line therapy for bladder cancer patients in one of the following clinical situations:
         I. Patient is not eligible for cisplatin-containing chemotherapy and tumors express PD-L1 confirmed by laboratory test results (PD-L1 expression is defined as PD-L1 stained tumor-infiltrating immune cells [IC] covering greater than or equal to 5% of the tumor area)
         II. Patient is not eligible for any platinum-containing chemotherapy regardless of PD-L1 status
      b. Documentation has been submitted showing at least one of the following:
         I. Stage II or Stage IIIa disease if tumor is present following reassessment of tumor status 2-3 months after primary treatment with concurrent chemoradiotherapy
         II. Stage IIIb disease as downstaging systemic therapy or following partial response or progression after primary treatment with concurrent chemoradiotherapy
         III. Locally advanced or metastatic disease
         IV. Metastatic or local recurrence post-cystectomy
         V. Muscle invasive local recurrence or persistent disease in a preserved bladder
   2. Urothelial Carcinoma - Primary Carcinoma of the Urethra
      a. Documentation has been submitted showing Tecentriq will be used as first-line therapy for recurrent, locally advanced or metastatic disease in patients in one of the following clinical situations:
         I. Patient is not eligible for cisplatin-containing chemotherapy and tumors express PD-L1 confirmed by laboratory test results (PD-L1 expression is defined as PD-L1 stained tumor-infiltrating immune cells [IC] covering greater than or equal to 5% of the tumor area)
         II. Patient is not eligible for any platinum-containing chemotherapy regardless of PD-L1 status

3. Urothelial Carcinoma - Upper Genitourinary Tract Tumors or Urothelial Carcinoma of the Prostate
    a. Documentation has been submitted showing Tecentriq will be used as first-line therapy for locally advanced or metastatic disease in patients in one of the following clinical situations:
        I. Patient is not eligible for cisplatin-containing chemotherapy and tumors express PD-L1 confirmed by laboratory test results (PD-L1 expression is defined as PD-L1 stained tumor-infiltrating immune cells [IC] covering greater than or equal to 5% of the tumor area)
        II. Patient is not eligible for any platinum-containing chemotherapy regardless of PD-L1 status
4. Non-Small Cell Lung Cancer (NSCLC)
    a. Documentation has been submitted showing the following;
        I. Patient's tumor is negative for EGFR, ALK, and RET gene mutations confirmed by laboratory test results (unless testing is not feasible due to insufficient tissue or if used in single agent subsequent therapy)
        II. Tecentriq will be used in one of the following clinical situations:
            - combination with bevacizumab, carboplatin and paclitaxel as first-line or subsequent* treatment of recurrent, advanced, or metastatic non-squamous NSCLC
            - combination with carboplatin and albumin-bound paclitaxel as first-line or subsequent* treatment of recurrent, advanced, or metastatic non-squamous NSCLC
                - * Subsequent therapy requires additional documentation showing the following
                    i. Patient has ROS1 rearrangement positive tumors confirmed with laboratory test results
                    ii. Patient has had prior treatment with crizotinib, entrectinib, or ceritinib
            - combination with bevacizumab as maintenance therapy after patient experiences tumor response or disease stability from a first-line non-squamous NSCLC treatment of a Tecentriq, carboplatin, paclitaxel and bevacizumab regimen, or Tecentriq, carboplatin, and albumin-bound paclitaxel regimen
            - Monotherapy as first-line treatment of recurrent, advanced, or metastatic disease in patients with PD-L1 greater than or equal to 50% as confirmed by laboratory test results
            - Monotherapy as subsequent treatment for recurrent, advanced, or metastatic disease
            - Monotherapy as as maintenance therapy after patient experiences tumor response or disease stability from a first-line monotherapy
            - Monotherapy as adjuvant treatment following resection and platinum-based chemotherapy for adult members with stage II to IIIA disease whose tumors have PD-L1 expression on # 1% of tumor cells
                - Hepatocellular Carcinoma (HCC)
                    1. Documentation has been submitted showing Tecentriq will be used in combination with bevacizumab as first-line treatment of unresectable or metastatic HCC
                - Melanoma
                    1. Documentation has been submitted showing the following:
                        1. Patietn has BRAF V600 mutation-positive unresectable or metastatic melanoma as confirmed by laboratory test results
                        2. Tecentriq will be used in combination with cobimetinib (Cotellic) and vemurafenib (Zelboraf)
5. Small Cell Lung Cancer (SCLC)
    a. Documentation has been submitted showing Tecentriq will be used in combination with etoposide and carboplatin as first-line treatment for extensive-stage SCLC, and then will be continued as monotherapy for maintenance
6. Hepatocellular Carcinoma (HCC)

a. Documentation has been submitted showing Tecentriq will be used in combination with bevacizumab as first-line treatment of unresectable or metastatic HCC

7. Melanoma
   a. Documentation has been submitted showing the following:
      I. Patietn has BRAF V600 mutation-positive unresectable or metastatic melanoma as confirmed by laboratory test results
      II. Tecentriq will be used in combination with cobimetinib (Cotellic) and vemurafenib (Zelboraf)

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval will be limited to 6 months of therapy
B. Continuation of therapy may be approved in 6-month intervals with documentation showing the patient is continuing to tolerate the regimen and there has not been disease progression while on treatment.

IV. EXCLUSIONS

A. Tecentriq will not be covered for the following:
   1. Patients that have experienced disease progression while on PD-1 or PDL1 inhibitor therapy
   2. Any indications or uses that are not FDA-approved, or guideline-supported

V. RECOMMENDED DOSAGE

Please refer to the FDA-approved prescribing information for indication-specific dosing details.

VI. CODES

Note: The following CPT/HCPCS codes are included below for informational purposes. Inclusion or exclusion of a CPT/ HCPCS code(s) below does not signify or imply member coverage or provider reimbursement. The member's specific benefit plan determines coverage.

Medication	HCPCS/CPT Code
Injection, atezolizumab, 10 mg	J9022

VII. REFERENCES

1. Tecentriq [prescribing information]. South San Francisco, CA: Genentech, Inc.; January 2022.
2. National Comprehensive Cancer Network Drugs & Biologics Compendium™. Available at: https://www.nccn.org. Accessed March 3, 2022.

VIII. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
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