Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology
Office of Pharmacovigilance and Epidemiology

Pediatric Postmarketing Pharmacovigilance Review

Date:	April 7, 2026
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Product Name:	Tecentriq (atezolizumab)
Pediatric Labeling Dates:	September 30, 2020 (Supplement-029) December 9, 2022 (Supplement-047)
Application Type/Number:	BLA 761034
Applicant:	Genentech, Inc
TTT Record ID:	2025-13995

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EXECUTIVE SUMMARY

This review evaluates FDA Adverse Event Reporting System (FAERS) reports for Tecentriq (atezolizumab) in pediatric patients less than 17 years of age. The Division of Pharmacovigilance (DPV) conducted this review in accordance with the Best Pharmaceuticals for Children Act (BPCA). This review focuses on United States (U.S.) serious unlabeled adverse events associated with atezolizumab in pediatric patients.

Tecentriq (atezolizumab) is a programmed death-ligand 1 (PD-L1) blocking antibody that was initially FDA approved on May 18, 2016. Atezolizumab is currently indicated for:

Non-Small Cell Lung Cancer (NSCLC)

- 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.
- 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 epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (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.
- 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.

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).
- in combination with lurbinectedin, for the maintenance treatment of adult patients with ES-SCLC whose disease has not progressed after first-line induction therapy with TECENTRIQ or atezolizumab and hyaluronidase-tqjs, carboplatin and etoposide.

Hepatocellular Carcinoma (HCC)

- in combination with bevacizumab for the treatment of adult patients with unresectable or metastatic HCC who have not received prior systemic therapy.

Melanoma

- in combination with cobimetinib and vemurafenib for the treatment of adult patients with BRAF V600 mutation-positive unresectable or metastatic melanoma.

Alveolar Soft Part Sarcoma (ASPS)

- the treatment of adult and pediatric patients 2 years of age and older with unresectable or metastatic ASPS.

This pediatric postmarketing safety review was prompted by the following pediatric labeling changes:

- September 30, 2020: Labeling updated to include findings from a clinical trial that assessed but did not establish safety and effectiveness in pediatric patients aged 7 months to <17 years with relapsed or progressive solid tumors and lymphomas.

- December 9, 2022: Labeling updated to reflect expanded indication that includes use in the treatment of adult and pediatric patients 2 years of age and older with unresectable or metastatic ASPS.

The safety and effectiveness of Tecentriq has not been established in pediatric patients younger than 2 years with ASPS, or in pediatric patients with NSCLC, SCLC, HCC, or melanoma.

DPV did not identify any new pediatric safety concerns for atezolizumab at this time and will continue routine pharmacovigilance monitoring for atezolizumab.

1 INTRODUCTION

This review evaluates FDA Adverse Event Reporting System (FAERS) reports for Tecentriq (atezolizumab) in pediatric patients less than 17 years of age. The Division of Pharmacovigilance (DPV) conducted this review in accordance with the Best Pharmaceuticals for Children Act (BPCA). This review focuses on United States (U.S.) serious unlabeled adverse events associated with atezolizumab in pediatric patients.

1.1 PEDIATRIC REGULATORY HISTORY

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- 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.

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The safety and effectiveness of Tecentriq has not been established in pediatric patients younger than 2 years with ASPS, or in pediatric patients with NSCLC, SCLC, HCC, or melanoma.

Atezolizumab has not previously been presented to the Pediatric Advisory Committee.

1.2 RELEVANT LABELED SAFETY INFORMATION

The Tecentriq labeling contains the following safety information excerpted from the Highlights of Prescribing Information and the *Pediatric Use* subsection. For additional Tecentriq labeling information, please refer to the full prescribing information.[1]

----------CONTRAINDICATIONS----------

- None.

----------WARNINGS AND PRECAUTIONS----------

- Immune-Mediated Adverse Reactions
  - Immune-mediated adverse reactions, which may be severe or fatal, can occur in any organ system or tissue, including the following: immune-mediated pneumonitis, immune-mediated colitis, immune-mediated hepatitis, immune-mediated endocrinopathies, immune-mediated dermatologic adverse reactions, immune-mediated nephritis and renal dysfunction, and solid organ transplant rejection.
  - Monitor for early identification and management. Evaluate liver enzymes, creatinine, and thyroid function at baseline and periodically during treatment.
  - Withhold or permanently discontinue based on severity and type of reaction.
- Infusion-Related Reactions: Interrupt, slow the rate of infusion, or permanently discontinue based on severity of infusion reactions.
- Complications of Allogeneic HSCT: Fatal and other serious complications can occur in patients who receive allogeneic HSCT before or after being treated with a PD-1/PD-L1 blocking antibody.
- Embryo-Fetal Toxicity: Can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and use of effective contraception.

----------ADVERSE REACTIONS----------

TECENTRIQ as a single-agent
- Most common adverse reactions (≥ 20%) with TECENTRIQ as a single-agent are fatigue/asthenia, decreased appetite, nausea, cough, and dyspnea.

TECENTRIQ in combination with other antineoplastic drugs
- Most common adverse reactions (≥ 20%) in patients with NSCLC and SCLC are fatigue/asthenia, nausea, alopecia, constipation, diarrhea, and decreased appetite.

TECENTRIQ in combination with bevacizumab
- Most common adverse reactions (≥ 20%) in patients with HCC are hypertension, fatigue and proteinuria.

TECENTRIQ in combination with cobimetinib and vemurafenib

- Most common adverse reactions (≥ 20%) with TECENTRIQ in patients with melanoma are rash, musculoskeletal pain, fatigue, hepatotoxicity, pyrexia, nausea, pruritus, edema, stomatitis, hypothyroidism, and photosensitivity reaction.

----------USE IN SPECIFIC POPULATIONS----------

8.4 Pediatric Use

Alveolar Soft Part Sarcoma
The safety and effectiveness of TECENTRIQ for unresectable or metastatic ASPS have been established in pediatric patients aged 2 years and older. Use of TECENTRIQ for this indication is supported by evidence from an adequate and well controlled study of TECENTRIQ in adults and 2 adolescent pediatric patients (≥12 years of age) with ASPS with additional pharmacokinetic and safety data in pediatric patients 2 years to <17 years. These data suggest that atezolizumab exposure in pediatric patients aged 2 years and older is comparable with that of adults and is expected to result in similar safety and efficacy to that of adults. The course of unresectable or metastatic ASPS is sufficiently similar between pediatric patients 2 to 11 years old and that of adults and adolescent patients to allow extrapolation of efficacy and safety to pediatric patients 2 years and older.

The safety and effectiveness of TECENTRIQ for ASPS have not been established in pediatric patients younger than 2 years of age.

Solid Tumors and Lymphomas
The safety and effectiveness of TECENTRIQ in pediatric patients have not been established in non-small cell lung cancer, small-cell lung cancer, hepatocellular carcinoma, or melanoma.

The safety and effectiveness of TECENTRIQ were assessed, but not established in a single-arm, multi-center, multi-cohort trial (NCT02541604) in 60 pediatric patients aged 7 months to <17 years with relapsed or progressive solid tumors and lymphomas. No new safety signals were observed in pediatric patients in this study.

2 METHODS AND MATERIALS

DPV searched the FAERS database with the strategy described in Table 1.

Table 1. FAERS Search Strategy[*]

Date of search	February 4, 2026
Time period of search	May 18, 2016[†] - February 3, 2026
Search type	RxLogix Pediatric Focused Review Alert – DPV
Product terms	Product Active Ingredient: atezolizumab
MedDRA search terms (Version 28.1)	All Preferred Terms

[*] See Appendix A for a description of the FAERS database.
[†] U.S. approval date for Tecentriq (atezolizumab)
Abbreviation: MedDRA=Medical Dictionary for Regulatory Activities

3 RESULTS

3.1 SELECTION OF U.S. SERIOUS PEDIATRIC CASES IN FAERS

Our FAERS search retrieved 22 U.S. serious[a] pediatric reports for patients less than 17 years old from May 18, 2016, through February 3, 2026, including three reports with the outcome of death. We excluded all 22 reports from the case series for the reasons described below:

- Duplicates (n=8, including 1 death)
- Labeled adverse event not representing increased severity (n=5)
- Adverse event more likely due to concomitant medications or comorbidities (n=5, including 2 deaths)
- Unassessable[b] (n=4)

Two excluded unique U.S. FAERS reports described fatal outcomes resulting from progression of primary neoplastic disease.

After excluding reports as described above, zero cases remained for discussion.

3.2 SUMMARY OF U.S. FATAL PEDIATRIC CASES (N=0)

There are no fatal pediatric adverse event cases for discussion.

3.3 SUMMARY OF U.S. SERIOUS NON-FATAL PEDIATRIC CASES (N=0)

There are no non-fatal pediatric adverse event cases for discussion.

4 DISCUSSION

DPV reviewed all U.S. serious FAERS reports with atezolizumab in pediatric patients less than 17 years of age from May 18, 2016, through February 3, 2026, and identified 22 reports; however, all reports were excluded from further discussion.

There were no new safety signals identified, no increased severity of any labeled adverse events, and no deaths directly associated with atezolizumab in pediatric patients less than 17 years of age.

5 CONCLUSION

DPV did not identify any new pediatric safety concerns for atezolizumab at this time and will continue routine pharmacovigilance monitoring for atezolizumab.

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[a] For the purposes of this review, the following outcomes qualify as serious: death, life-threatening, hospitalization (initial or prolonged), disability, congenital anomaly, required intervention, or other serious important medical events.

[b] Unassessable reports are those that cannot be assessed for causality because there is insufficient information reported (i.e., unknown time to event, concomitant medications and comorbidities, clinical course and outcome), the information is contradictory, or information provided in the report cannot be supplemented or verified.

6 REFERENCES

1. Tecentriq (atezolizumab) [package insert]. South San Francisco, CA: Genentech, Inc; 2025.

7 APPENDICES

7.1 APPENDIX A. FDA ADVERSE EVENT REPORTING SYSTEM (FAERS)

The FDA Adverse Event Reporting System (FAERS) is a database that contains information on adverse event and medication error reports submitted to FDA. The database is designed to support FDA's postmarketing safety surveillance program for drug and therapeutic biological products. The informatic structure of the database adheres to the international safety reporting guidance issued by the International Council on Harmonisation. Adverse events and medication errors are coded to terms in the Medical Dictionary for Regulatory Activities terminology. The suspect products are coded to valid tradenames or active ingredients in the FAERS Product Dictionary.

FAERS data have limitations. First, there is no certainty that the reported event was actually due to the product. FDA does not require that a causal relationship between a product and event be proven, and reports do not always contain enough detail to properly evaluate an event. Further, FDA does not receive reports for every adverse event or medication error that occurs with a product. Many factors can influence whether an event will be reported, such as the time a product has been marketed and publicity about an event. Therefore, FAERS data cannot be used to calculate the incidence of an adverse event or medication error in the U.S. population.