Navigating Payer Reimbursement flash cards

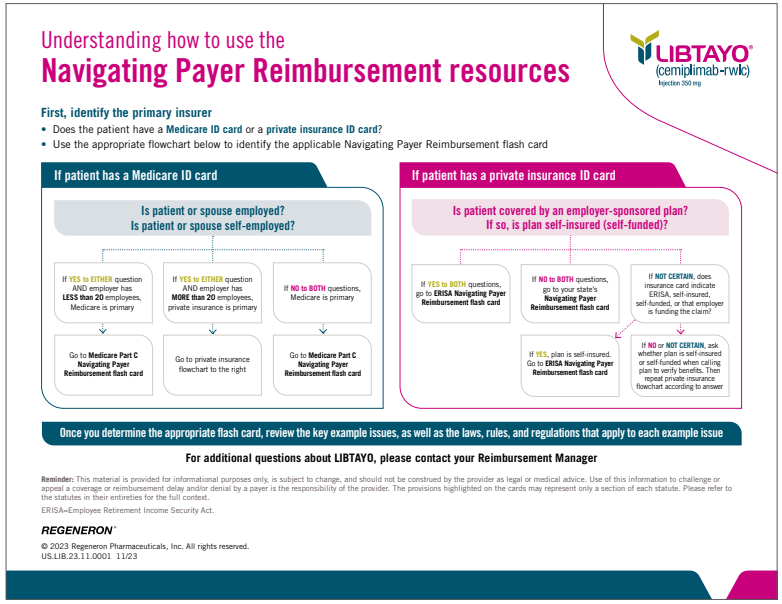
The Navigating Payer Reimbursement suite of resources was developed for providers who prescribe LIBTAYO® (cemiplimab-rwlc). It includes a user guide, state-specific flash cards, and additional resources for ERISA and Medicare Part C

These resources will:

- **Provide information on helping to navigate insurance and reimbursement issues** that may arise as they pertain to federal and state insurance laws, rules, and regulations
- **Provide state-specific information** on commonly encountered reimbursement issues, including prior authorization, prompt payment, request for additional information, and provider appeals
- **Help identify which provisions apply to common issues**, based on a patient's coverage
- **Help providers understand options** regarding payer decisions and reimbursement

Interested in learning more?

Please reach out to Melissa Souders, melissa.souders@regeneron.com, with any questions and to receive access to these resources



Understanding how to use the
Navigating Payer Reimbursement resources

LIBTAYO® (cemiplimab-rwlc) Injection 350 mg

First, identify the primary insurer

- Does the patient have a **Medicare ID card** or a **private insurance ID card**?
- Use the appropriate flowchart below to identify the applicable Navigating Payer Reimbursement flash card

If patient has a Medicare ID card

Is patient or spouse employed?
Is patient or spouse self-employed?

- If **YES to EITHER** question AND employer has **LESS than 20** employees, Medicare is primary → Go to **Medicare Part C Navigating Payer Reimbursement flash card**
- If **YES to EITHER** question AND employer has **MORE than 20** employees, private insurance is primary → Go to private insurance flowchart to the right
- If **NO to BOTH** questions, Medicare is primary → Go to **Medicare Part C Navigating Payer Reimbursement flash card**

If patient has a private insurance ID card

Is patient covered by an employer-sponsored plan?
If so, is plan self-insured (self-funded)?

- If **YES to BOTH** questions, go to **ERISA Navigating Payer Reimbursement flash card**
- If **NO to BOTH** questions, go to your state's **Navigating Payer Reimbursement flash card**
- If **NOT CERTAIN**, does insurance card indicate ERISA, self-insured, self-funded, or that employer is funding the claim?
  - If **YES**, plan is self-insured. Go to **ERISA Navigating Payer Reimbursement flash card**
  - If **NO** or **NOT CERTAIN**, ask whether plan is self-insured or self-funded when calling plan to verify benefits. Then repeat private insurance flowchart according to answer

Once you determine the appropriate flash card, review the key example issues, as well as the laws, rules, and regulations that apply to each example issue

For additional questions about LIBTAYO, please contact your Reimbursement Manager

Reminder: This material is provided for informational purposes only, is subject to change, and should not be construed by the provider as legal or medical advice. Use of this information to challenge or appeal a coverage or reimbursement delay and/or denial by a payer is the responsibility of the provider. The provisions highlighted on the cards may represent only a section of each statute. Please refer to the statutes in their entireties for the full context.

ERISA=Employee Retirement Income Security Act.

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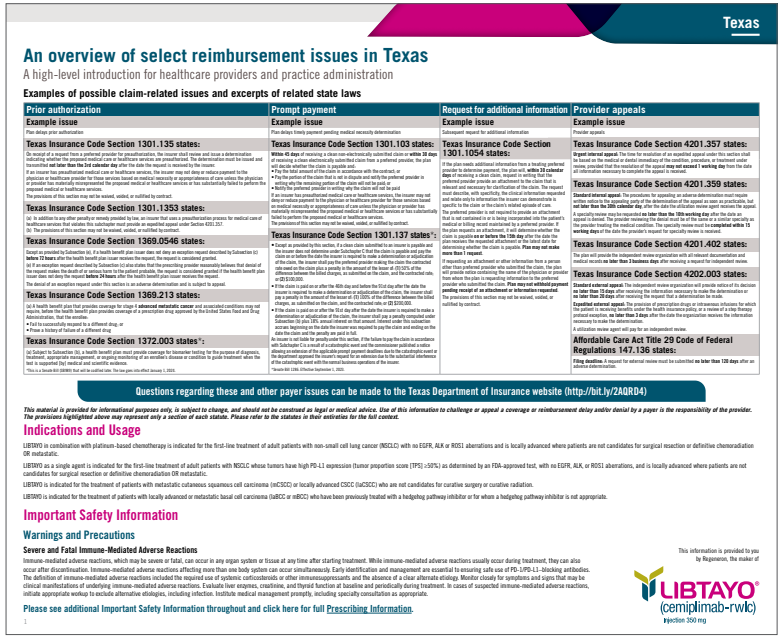

Texas

An overview of select reimbursement issues in Texas
A high-level introduction for healthcare providers and practice administration

Examples of possible claim-related issues and excerpts of related state laws

Prior authorization	Prompt payment	Request for additional information	Provider appeals
Example issue	**Example issue**	**Example issue**	**Example issue**
Pre-delay prior authorization	Plan delays timely payment pending medical necessity determination	Subsequent request for additional information	Provider appeals
Texas Insurance Code Section 1301.135 states: Do receipt of a request from a preferred provider for preauthorization, the insurer shall review and issue a determination indicating whether the proposed medical care or healthcare services are preauthorized. The determination must be issued and transmitted **not later than the 3rd calendar day** after the date the request is received by the insurer. If an insurer has preauthorized medical care or healthcare services, the insurer may not deny or reduce payment to the physician or healthcare provider for those services based on medical necessity or appropriateness of care unless the physician or provider has materially misrepresented the proposed medical or healthcare services or has substantially failed to perform the proposed medical or healthcare services. The provisions of this section may not be waived, voided, or nullified by contract.	**Texas Insurance Code Section 1301.103 states:** **Within 45 days** of receiving a clean non-electronically submitted claim or **within 30 days** of receiving a clean electronically submitted claim from a preferred provider, the plan will decide whether the claim is payable and: • Pay the total amount of the claim in accordance with the contract, or • Pay the portion of the claim that is not in dispute and notify the preferred provider in writing why the claim is not payable in accordance with the contract. • Notify the preferred provider in writing why the claim will not be paid. If an insurer has preauthorized medical care or healthcare services, the insurer may not deny or reduce payment to the physician or healthcare provider for those services based on medical necessity or appropriateness of care unless the physician or provider has materially misrepresented the proposed medical or healthcare services or has substantially failed to perform the proposed medical or healthcare services. The provisions of this section may not be waived, voided, or nullified by contract.	**Texas Insurance Code Section 1301.1054 states:** If the plan needs additional information from a treating preferred provider to determine payment, the plan will, **within 30 calendar days** of receiving a clean claim, request in writing that the preferred provider submit the information that the plan reasonably is relevant and necessary for clarification of the claim. The request must describe, with specificity, the clinical information requested and relate only to information the insurer can demonstrate is specific to the claim or the claim's related episode of care. The preferred provider is not required to provide an attachment that is not contained in or is being incorporated into the patient's medical record. If a preferred provider submits an attachment to the plan requests an attachment, it will determine whether the claim is payable **on or before the 15th day** after the date the plan receives the requested attachment or the latest date for determining whether the claim is payable. **Plan may not make more than 1 request.** If requesting an attachment or other information from a person other than a preferred provider, the plan will request that the person will provide notice containing the name of the physician or provide from whom the plan is requesting information to the preferred provider who submitted the claim. **Plan may not withhold payment pending receipt of an attachment or information requested.** The provisions of this section may not be waived, voided, or nullified by contract.	**Texas Insurance Code Section 4201.357 states:** **Urgent internal appeal:** The time for resolution of an expedited appeal under this section shall be based on the medical or dental immediacy of the condition, ceteraion, or treatment under review, provided that the resolution of the appeal **may not exceed 1 working day** from the date all information necessary to complete the appeal is received. **Texas Insurance Code Section 4201.359 states:** **Standard internal appeal:** The procedures for appealing an adverse determination must require written notice to the appealing party of the determination of the appeal as soon as practicable, but **not later than the 30th calendar day** after the date the utilization review agent receives the appeal. A specialty review may be requested **no later than the 10th working day** after the date an appeal is denied. The provider reviewing the dental must be of the same or a similar specialty as the provider treating the medical condition. The specialty review must be **completed within 15 working days** of the date the provider's request for specialty review is received. **Texas Insurance Code Section 4201.402 states:** The plan will provide the independent review organization with all relevant documentation and medical records **no later than 3 business days** after receiving a request for independent review. **Texas Insurance Code Section 4202.003 states:** **Standard external appeal:** The independent review organization will provide notice of its decision **no later than 15 days** after receiving the information necessary to make the determination or **no later than 20 days** after receiving the request that a determination be made. **Expedited external appeal:** The provision of prescription drugs or intravenous infusions for which the patient is receiving benefits under the health insurance policy, or a review of a step therapy protocol exception, **no later than 3 days** after the date the organization receives the information necessary to make the determination. A utilization review agent will pay for an independent review. **Affordable Care Act Title 29 Code of Federal Regulations 147.136 states:** **Filing deadline.** A request for external review must be submitted **no later than 120 days** after an adverse determination.
Texas Insurance Code Section 1301.1353 states: (a) In addition to any other penalty or remedy provided by law, an insurer that uses a preauthorization process for medical care of healthcare services shall pay a fine for each violation of a requirement imposed by or adopted under Section 4201.257. (b) The provisions of this section may not be waived, voided, or nullified by contract.	**Texas Insurance Code Section 1301.137 states*:** • Except as provided by this section, if a clean claim submitted to an insurer is payable but the plan fails to pay the entire amount of the claim or fails to deny payment of the claim or fails to deny the claim in whole or in part before the date the insurer is required to make a determination or adjudication of the claim, the insurer shall pay the preferred provider making the claim the contracted rate based on the claim plus a penalty in the amount of the lesser of: (1) 50% of the difference between the billed charges, as submitted on the claim, and the contracted rate, or (2) $250,000. • If the claim is paid on or after the 45th day and before the 91st day after the date the insurer is required to make a determination or adjudication of the claim, the insurer shall pay a penalty computed under Subsection (c) of this section. • If the claim is paid on or after the 91st day after the date the insurer accrues, beginning on the date the insurer was required to pay the claim and ending on the date the claim and the penalty are paid in full. An insurer is not liable for penalty under this section, if the failure to pay the claim in accordance with Subchapter C is a result of a catastrophic event and the commissioner published a notice in the Texas Register stating that a catastrophic event has occurred. Notwithstanding the foregoing, the department approved the insurer's request for an extension due to the substantial interference of the catastrophic event with the normal business operations of the insurer. *Senate Bill 1196, Effective September 1, 2019.		
Texas Insurance Code Section 1369.213 states: (a) A health benefit plan that provides coverage for stage 4 **advanced metastatic cancer** and associated conditions may not require, before the health benefit plan provides coverage of a prescription drug approved by the United States Food and Drug Administration, that the enrollee: • Fail to successfully respond to a different drug, or • Prove a history of failure of a different drug.			
Texas Insurance Code Section 1372.003 states*: (a) Subject to Subsection (b), a health benefit plan must provide coverage for biomarker testing for the purpose of diagnosis, treatment, appropriate management, or ongoing monitoring of an enrollee's disease or condition to guide treatment when the test is supported by medical and scientific evidence. *This is a Senate Bill (SB)#86 that will be codified later. The law goes into effect January 1, 2020.			

Questions regarding these and other payer issues can be made to the Texas Department of Insurance website (http://bit.ly/2AQRD4)

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Indications and Usage

LIBTAYO in combination with platinum-based chemotherapy is indicated for the first-line treatment of adult patients with non-small cell lung cancer (NSCLC) with no EGFR, ALK or ROS1 aberrations and is locally advanced where patients are not candidates for surgical resection or definitive chemoradiation OR metastatic.

LIBTAYO as a single agent is indicated for the first-line treatment of adult patients with NSCLC whose tumors have high PD-L1 expression (tumor proportion score [TPS] ≥50%) as determined by an FDA-approved test, with no EGFR, ALK, or ROS1 aberrations, and is locally advanced where patients are not candidates for surgical resection or definitive chemoradiation OR metastatic.

LIBTAYO is indicated for the treatment of patients with metastatic cutaneous squamous cell carcinoma (mCSCC) or locally advanced CSCC (laCSCC) who are not candidates for curative surgery or curative radiation.

LIBTAYO is indicated for the treatment of patients with locally advanced or metastatic basal cell carcinoma (laBCC or mBCC) who have been previously treated with a hedgehog pathway inhibitor or for whom a hedgehog pathway inhibitor is not appropriate.

Important Safety Information

Warnings and Precautions

Severe and Fatal Immune-Mediated Adverse Reactions

Immune-mediated adverse reactions, which may be severe or fatal, can occur in any organ system or tissue at any time after starting treatment. While immune-mediated adverse reactions usually occur during treatment, they can also occur after discontinuation. Immune-mediated adverse reactions affecting more than one body system can occur simultaneously. Early identification and management are essential to ensuring safe use of PD-1/PD-L1-blocking antibodies. The definition of immune-mediated adverse reactions included the required use of systemic corticosteroids or other immunosuppressants and the absence of a clear alternate etiology. Monitor closely for symptoms and signs that may be clinical manifestations of underlying immune-mediated adverse reactions. Evaluate liver enzymes, creatinine, and thyroid function at baseline and periodically during treatment. In cases of suspected immune-mediated adverse reactions, initiate appropriate workup to exclude alternative etiologies, including infection. Institute medical management promptly, including specialty consultation as appropriate.

Please see additional Important Safety Information throughout and click here for full Prescribing Information.

This information is provided to you by Regeneron, the maker of LIBTAYO® (cemiplimab-rwlc) Injection 350 mg

ERISA=Employee Retirement Income Security Act.