AUGTYRO™ (repotrectinib) 40 mg capsules

Bristol Myers Squibb®

Access Support®

Your patient. Our commitment.

A REFERENCE GUIDE TO

Billing and Coding

AUGTYRO® (repotrectinib)

Please see Important Safety Information on pages 13–15 and U.S. Full Prescribing Information for AUGTYRO.

Indications

***ROS1*-Positive Non-Small Cell Lung Cancer**

AUGTYRO is indicated for the treatment of adult patients with locally advanced or metastatic *ROS1*-positive non-small cell lung cancer-positive NSCLC.

***NTRK* Gene Fusion-Positive Solid Tumors**

AUGTYRO is indicated for the treatment of adult and pediatric patients 12 years of age and older with solid tumors that:
- have a neurotrophic tyrosine receptor kinase (*NTRK*) gene fusion,
- are locally advanced or metastatic or where surgical resection is likely to result in severe morbidity, and
- have progressed following treatment or have no satisfactory alternative therapy.

This indication is approved under accelerated approval based on overall 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).

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) recommendations for repotrectinib (AUGTYRO)[1*]

NSCLC: NCCN Category 2A Preferred
Repotrectinib (AUGTYRO) is recommended as a Category 2A, preferred first-line therapy option for patients with NSCLC and *ROS1* rearrangement.
Repotrectinib (AUGTYRO) is recommended as a Category 2A, preferred first-line treatment option and subsequent treatment option (if not previously given) for patients that have an *NTRK* 1/2/3 gene fusion-positive NSCLC.[†]

*For full recommendations, please see NCCN Guidelines®
[†]Advanced or metastatic.

SUMMARY OF WARNINGS AND PRECAUTIONS
AUGTYRO (repotrectinib) is associated with the following warnings and precautions: central nervous system (CNS) adverse reactions, interstitial lung disease (ILD)/pneumonitis, hepatotoxicity, myalgia with creatine phosphokinase (CPK) elevation, hyperuricemia, skeletal fractures, and embryo-fetal toxicity.

At Bristol Myers Squibb, We Provide Support With Purpose

This brochure is designed to help appropriate patients gain access to their prescribed BMS medications by providing reimbursement information for healthcare offices. Healthcare benefits vary significantly; therefore, it is important that healthcare provider offices verify each patient's insurance coverage prior to initiating therapy.

Table of Contents

Healthcare providers should code healthcare claims based upon the service that is rendered, the patient's medical record, the coding requirements of each health insurer, and the best coding practices. The HCP and patient are responsible for the accurate completion of documents regarding reimbursement or coverage. Bristol Myers Squibb and its agents make no guarantee regarding reimbursement for any service or item.

ICD-10-CM=International Classification of Diseases; NDC=National Drug Code.

NDC Information for AUGTYRO

The NDCs for AUGTYRO are listed below.

NDCs for AUGTYRO[2]

 40 mg capsules	One bottle containing 60 capsules 00003-4040-60	
	One bottle containing 120 capsules 00003-4040-12	
 160 mg capsule	One bottle containing 14 capsules 00003-4160-14	
	One bottle containing 60 capsules 00003-4160-60	

The red zero (red text) converts the 10-digit NDC to the 11-digit NDC. Payer requirements regarding the use of NDCs may vary. Electronic data exchange generally requires the use of an 11-digit NDC.

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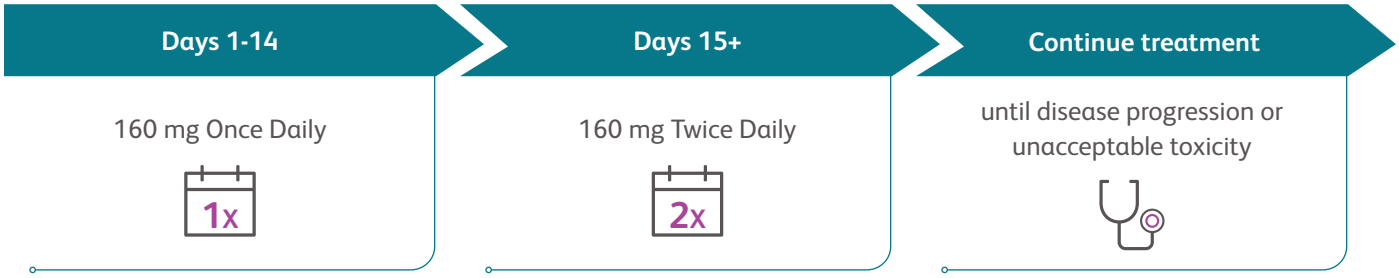
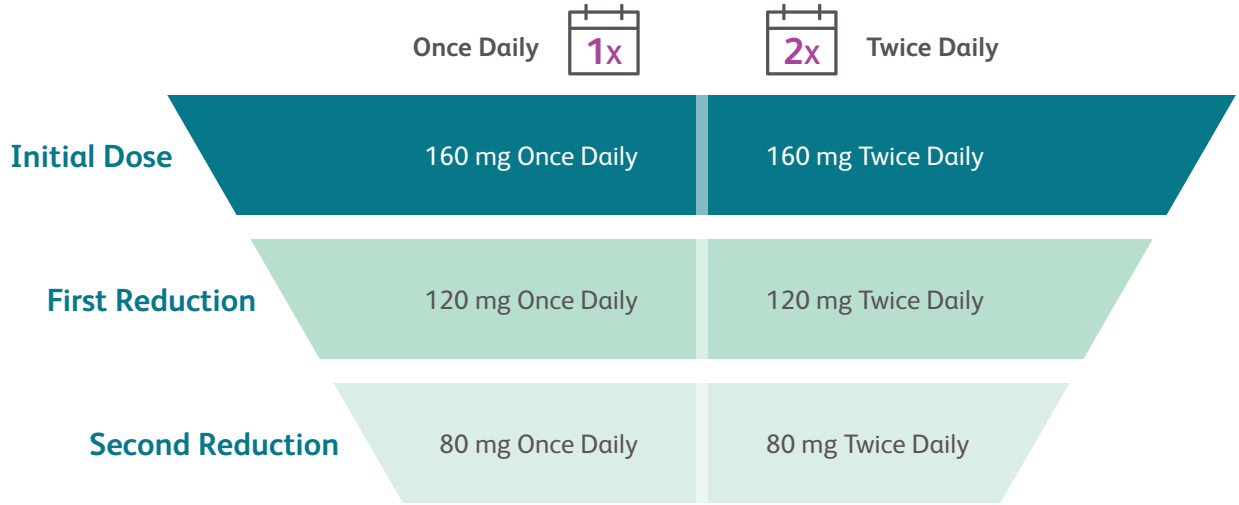
Dosage and Administration for AUGTYRO

Recommended Dosage for Adult and Pediatric Patients 12 Years of Age and Older With Locally Advanced or Metastatic *ROS1*+ NSCLC and Locally Advanced or Metastatic *NTRK* Gene Fusion-Positive Solid Tumors[2]



Recommended Dosage Reductions for Adverse Reactions[2]



Important Dosing Information[2]

AUGTYRO may be taken with or without food. Patients should swallow capsules whole at the same time every day as prescribed.

Advise patients to avoid grapefruit juice.

Capsules should not be opened, broken, crushed, or dissolved. If a dose is missed or if a patient vomits at any time after taking a dose, patients should resume subsequent doses as prescribed.

Withhold AUGTYRO if Interstitial Lung Disease (ILD)/pneumonitis is suspected and permanently discontinue treatment if confirmed.

Please see Section 2, DOSAGE AND ADMINISTRATION, of the U.S. Full Prescribing Information for additional information on dose modifications for Central Nervous System Effects, ILD/pneumonitis, and other clinically relevant adverse reactions.

Effective July 1

Specialty Pharmacies and Distributors

Specialty Pharmacies	Phone	Fax	URL
Onco360	877-662-6633	877-662-6355	www.onco360.com
Biologics	800-850-4306	800-823-4506	biologics.mckesson.com
Specialty Distributors	**Phone**	**Fax**	**URL**
Physician Offices			
Biocare SD	800-304-3064	NA	store.biocaresd.com/biocare/en/ USD/login
Cardinal Health Specialty Pharmaceutical Distribution	866-677-4844	614-553-6301	specialtyonline.cardinalhealth.com
Curascript	877-599-7748	NA	www.curascriptsd.com
Oncology Supply	800-633-7555	NA	www.oncologysupply.com
Besse Medical	888-711-5469	NA	www.besse.com
McKesson Specialty Health	800-482-6700	NA	mscs.mckesson.com
Morris & Dickson Specialty	800-710-6100	318-524-3096	www.mdspecialtydist.com
Hospitals/Institutions			
Cardinal Health Specialty Pharmaceutical Distribution	866-677-4844	614-553-6301	orderexpress.cardinalhealth.com
Curascript	877-599-7748	NA	www.curascriptsd.com
ASD Healthcare	800-746-6273	800-547-9413	www.asdhealthcare.com
McKesson Plasma & Biologics	877-625-2566	888-752-7626	connect.mckesson.com
Morris & Dickson Specialty	800-710-6100	318-524-3096	www.mdspecialtydist.com

For more information on how to order in Puerto Rico, visit BMSAccessSupport.com

AUGTYRO can also be procured by the practice directly from one of the authorized distributors in the list above. Please ensure your practice has the durable medical equipment (DME) license in place to bill the appropriate DME Medicare Administrative Contractor (DME MAC).

ICD-10-CM Code Overview[3]

ICD-10-CM codes are used to identify a patient's diagnosis.

- The ICD-10-CM diagnosis codes contain **categories**, **subcategories**, and **codes**. Characters for categories, subcategories, and codes may be letters or numerals
- **All categories** are 3 characters
- **Subcategories** are either 4 or 5 characters
- **Codes** may be 3, 4, 5, 6, or 7 characters

The ICD-10-CM codes for the labeled indication for AUGTYRO are provided by Bristol Myers Squibb and should be verified with the payer.

Some health plan and Medicare insurers may specify which codes are covered under their policies. Please code to the level of specificity documented in the medical record. For additional coding questions, call BMS Access Support® at **1-800-861-0048** or visit **www.BMSAccessSupport.com**.

This guide does not contain a comprehensive list of all possible ICD-10-CM codes. Please visit **icd10cmtool.cdc.gov** to search for applicable codes.

ROS1+ NSCLC ICD-10-CM Codes[3]

ICD-10-CM Codes for *ROS1*+ NSCLC[3]	
C33	**Malignant neoplasm of trachea**
C34.0	**Malignant neoplasm of main bronchus**
C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.1	**Malignant neoplasm of upper lobe, bronchus or lung**
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	**Malignant neoplasm of middle lobe, bronchus or lung**
C34.3	**Malignant neoplasm of lower lobe, bronchus or lung**
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.8	**Malignant neoplasm of overlapping sites of bronchus and lung**
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus and lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.9	**Malignant neoplasm of unspecified part of bronchus or lung**
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung

The HCP and patient are responsible for the accurate completion of documents regarding reimbursement or coverage. Bristol Myers Squibb and its agents make no guarantee regarding reimbursement for any service or item. This is not a comprehensive list of ICD-10-CM codes.

NTRK ICD-10-CM Codes[3]

Diagnosis	Code	Description
Breast Cancer	C50	Malignant neoplasm of breast
	C50.0	Malignant neoplasm of nipple and areola
	C50.01–C50.019	Malignant neoplasm of nipple and areola, female
	C50.02–C50.029	Malignant neoplasm of nipple and areola, male
	C50.1	Malignant neoplasm of central portion of breast
	C50.11–C50.119	Malignant neoplasm of central portion of breast, female
	C50.12–C50.129	Malignant neoplasm of central portion of breast, male
	C50.2	Malignant neoplasm of upper-inner quadrant of breast
	C50.21–C50.219	Malignant neoplasm of upper-inner quadrant of breast, female
	C50.22–C50.229	Malignant neoplasm of upper-inner quadrant of breast, male
	C50.3	Malignant neoplasm of lower-inner quadrant of breast
	C50.31–C50.319	Malignant neoplasm of lower-inner quadrant of breast, female
	C50.32–C50.329	Malignant neoplasm of lower-inner quadrant of breast, male
	C50.4	Malignant neoplasm of upper-outer quadrant of breast
	C50.41–C50.419	Malignant neoplasm of upper-outer quadrant of breast, female
	C50.42–C50.429	Malignant neoplasm of upper-outer quadrant of breast, male
	C50.5	Malignant neoplasm of lower-outer quadrant of breast
	C50.51–C50.519	Malignant neoplasm of lower-outer quadrant of breast, female
	C50.52–C50.529	Malignant neoplasm of lower-outer quadrant of breast, male
	C50.6	Malignant neoplasm of axillary tail of breast
	C50.61–C50.619	Malignant neoplasm of axillary tail of breast, female
	C50.62–C50.629	Malignant neoplasm of axillary tail of breast, male
	C50.8	Malignant neoplasm of overlapping sites of breast
	C50.81–C50.819	Malignant neoplasm of overlapping sites of breast, female
	C50.82–C50.829	Malignant neoplasm of overlapping sites of breast, male
	C50.9	Malignant neoplasm of breast of unspecified site
	C50.91–C50.919	Malignant neoplasm of breast of unspecified site, female
	C50.92–C50.929	Malignant neoplasm of breast of unspecified site, male
Cholangiocarcinoma	C22.1	Intrahepatic bile duct carcinoma
Colorectal Cancer	C18	Malignant neoplasm of colon
	C18.0	Malignant neoplasm of cecum
	C18.1	Malignant neoplasm of appendix
	C18.2	Malignant neoplasm of ascending colon
	C18.3	Malignant neoplasm of hepatic flexure
	C18.4	Malignant neoplasm of transverse colon
	C18.5	Malignant neoplasm of splenic flexure
	C18.6	Malignant neoplasm of descending colon
	C18.7	Malignant neoplasm of sigmoid colon
	C18.8	Malignant neoplasm of overlapping sites of colon
	C18.9	Malignant neoplasm of colon, unspecified
	C19	Malignant neoplasm of rectosigmoid junction

NTRK ICD-10-CM Codes[3] (cont'd)

Diagnosis	Code	Description
Colorectal Cancer (cont'd)	**C20**	**Malignant neoplasm of rectum**
	C21.8	**Malignant neoplasm of overlapping sites of rectum, anus and anal canal**
	C48	**Malignant neoplasm of retroperitoneum and peritoneum**
	C48.0	Malignant neoplasm of retroperitoneum
	C48.1	Malignant neoplasm of specified parts of peritoneum
	C48.2	Malignant neoplasm of peritoneum, unspecified
	C48.8	Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum
Gynecological Cancers	**C52**	**Malignant neoplasm of vagina**
	C53-C53.9	**Malignant neoplasm of cervix uteri**
	C54-C54.9	**Malignant neoplasm of corpus uteri**
	C55	**Malignant neoplasm of uterus, part unspecified**
	C56-C56.9	**Malignant neoplasm of ovary**
	C57	**Malignant neoplasm of other and unspecified female genital organs**
	C57.0	Malignant neoplasm of fallopian tube
	C57.00	Malignant neoplasm of unspecified fallopian tube
	C57.01	Malignant neoplasm of right fallopian tube
	C57.02	Malignant neoplasm of left fallopian tube
	C57.7	Malignant neoplasm of other specified female genital organs
	C57.8	Malignant neoplasm of overlapping sites of female genital organs
	C57.9	Malignant neoplasm of female genital organ, unspecified
Neuroendocrine Cancer	**C7A**	**Malignant neuroendocrine tumors**
	C7A.0	**Malignant carcinoid tumors**
	C7A.00	Malignant carcinoid tumor of unspecified site
	C7A.01	Malignant carcinoid tumors of the small intestine
	C7A.010	Malignant carcinoid tumor of the duodenum
	C7A.011	Malignant carcinoid tumor of the jejunum
	C7A.012	Malignant carcinoid tumor of the ileum
	C7A.019	Malignant carcinoid tumor of the small intestine, unspecified portion
	C7A.02	**Malignant carcinoid tumors of the appendix, large intestine, and rectum**
	C7A.020	Malignant carcinoid tumor of the appendix
	C7A.021	Malignant carcinoid tumor of the cecum
	C7A.022	Malignant carcinoid tumor of the ascending colon
	C7A.023	Malignant carcinoid tumor of the transverse colon
	C7A.024	Malignant carcinoid tumor of the descending colon
	C7A.025	Malignant carcinoid tumor of the sigmoid colon
	C7A.026	Malignant carcinoid tumor of the rectum
	C7A.029	Malignant carcinoid tumor of the large intestine, unspecified portion
	C7A.09	**Malignant carcinoid tumor of other sites**
	C7A.090	Malignant carcinoid tumor of the bronchus and lung
	C7A.091	Malignant carcinoid tumor of the thymus

NTRK ICD-10-CM Codes[3] (cont'd)

Diagnosis	Code	Description
Neuroendocrine Cancer (cont'd)	C7A.092	Malignant carcinoid tumor of the stomach
	C7A.093	Malignant carcinoid tumor of the kidney
	C7A.094	Malignant carcinoid tumor of the foregut, unspecified
	C7A.095	Malignant carcinoid tumor of the midgut, unspecified
	C7A.096	Malignant carcinoid tumor of the hindgut, unspecified
	C7A.098	Malignant carcinoid tumor of other sites
	C7A.1	**Malignant poorly differentiated neuroendocrine tumors**
	C7A.8	**Other malignant neuroendocrine tumors**
Non-small Cell Lung Cancer	**C33**	**Malignant neoplasm of trachea**
	C34.0	**Malignant neoplasm of main bronchus**
	C34.00	Malignant neoplasm of unspecified main bronchus
	C34.01	Malignant neoplasm of right main bronchus
	C34.02	Malignant neoplasm of left main bronchus
	C34.1	**Malignant neoplasm of upper lobe, bronchus or lung**
	C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
	C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
	C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
	C34.2	**Malignant neoplasm of middle lobe, bronchus or lung**
	C34.3	**Malignant neoplasm of lower lobe, bronchus or lung**
	C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
	C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
	C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
	C34.8	**Malignant neoplasm of overlapping sites of bronchus and lung**
	C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus and lung
	C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
	C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
	C34.9	**Malignant neoplasm of unspecified part of bronchus or lung**
	C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
	C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
	C34.92	Malignant neoplasm of unspecified part of left bronchus or lung
Pancreatic Cancer	**C25-C25.9**	**Malignant neoplasm of pancreas**
Mammary Analogue Secretory Carcinoma	**C07**	**Malignant neoplasm of parotid gland**
	C08	**Malignant neoplasm of other and unspecified major salivary glands**
	C08.0	Malignant neoplasm of submandibular gland
	C08.1	Malignant neoplasm of sublingual gland
	C08.9	Malignant neoplasm of major salivary gland, unspecified
Sarcoma	**C47-C47.9**	**Malignant neoplasm of peripheral nerves and autonomic nervous system**
	C48-C48.8	**Malignant neoplasm of retroperitoneum and peritoneum**

NTRK ICD-10-CM Codes[3] (cont'd)

Diagnosis	Code	Description
Sarcoma (cont'd)	C49-C49.9	Malignant neoplasm of other connective and soft tissue
	C49.A-C49.A9	Gastrointestinal stromal tumor
	C40-C40.92	Malignant neoplasm of bone and articular cartilage of limbs
	C41-C41.9	Malignant neoplasm of bone and articular cartilage of other and unspecified sites
Thyroid Cancer	C73	Malignant neoplasm of thyroid gland
Melanoma	C43-C43.9	Malignant melanoma of skin
Primary Central Nervous System	C71	Malignant neoplasm of brain
	C71.0	Malignant neoplasm of cerebrum, except lobes and ventricles
	C71.1	Malignant neoplasm of frontal lobe
	C71.2	Malignant neoplasm of temporal lobe
	C71.3	Malignant neoplasm of parietal lobe
	C71.4	Malignant neoplasm of occipital lobe
	C71.5	Malignant neoplasm of cerebral ventricle
	C71.6	Malignant neoplasm of cerebellum
	C71.7	Malignant neoplasm of brain stem
	C71.8	Malignant neoplasm of overlapping sites of brain
	C71.9	Malignant neoplasm of brain, unspecified
Hepatocellular Cancer	C22.0	Liver cell carcinoma
Mesothelioma	C45.0	Mesothelioma of pleura
	C45.1	Mesothelioma of peritoneum

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Indications and Important Safety Information

INDICATIONS

AUGTYRO® is indicated for the treatment of:

- adult patients with locally advanced or metastatic *ROS1*-positive non-small cell lung cancer (NSCLC)
- adult and pediatric patients 12 years of age and older with solid tumors that:
  - have a neurotrophic tyrosine receptor kinase (*NTRK*) gene fusion,
  - are locally advanced or metastatic or where surgical resection is likely to result in severe morbidity, and
  - have progressed following treatment or have no satisfactory alternative therapy

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

IMPORTANT SAFETY INFORMATION

Warnings & Precautions

Central Nervous System Adverse Reactions

- Among the 426 patients who received AUGTYRO in Study TRIDENT-1, a broad spectrum of central nervous system (CNS) adverse reactions including dizziness, ataxia, and cognitive disorders occurred in 77% of patients with Grade 3 or 4 events occurring in 4.5%.
- Dizziness, including vertigo, occurred in 65%; Grade 3 dizziness occurred in 2.8% of patients.
- Ataxia, including gait disturbance and balance disorder, occurred in 28% of patients; Grade 3 ataxia occurred in 0.5%.
- Cognitive impairment, including memory impairment and disturbance in attention, occurred in 25% of patients. Cognitive impairment included memory impairment (15%), disturbance in attention (12%), and confusional state (2%); Grade 3 cognitive impairment occurred in 0.9% of patients.
- Mood disorders occurred in 6% of patients. Mood disorders occurring in >1% of patients included anxiety (2.6%); Grade 4 mood disorders (mania) occurred in 0.2% of patients.
- Sleep disorders including insomnia and hypersomnia occurred in 18% of patients. Sleep disorders observed in >1% of patients were somnolence (9%), insomnia (6%) and hypersomnia (1.6%).
- The incidences of CNS adverse reactions reported were similar in patients with and without CNS metastases.
- Advise patients not to drive or use machines if they are experiencing CNS adverse reactions. Withhold and then resume at same or reduced dose upon improvement, or permanently discontinue AUGTYRO based on severity.

Interstitial Lung Disease (ILD)/Pneumonitis

- Among the 426 patients treated with AUGTYRO, ILD/pneumonitis (pneumonitis [2.8%] and ILD [0.2%]) occurred in 3.1%; Grade 3 ILD/pneumonitis occurred in 1.2%.
- Monitor patients for new or worsening pulmonary symptoms indicative of ILD/pneumonitis. Immediately withhold AUGTYRO in patients with suspected ILD/pneumonitis and permanently discontinue AUGTYRO if ILD/pneumonitis is confirmed.

Important Safety Information (cont'd)

Hepatotoxicity

- Among the 426 patients treated with AUGTYRO, increased alanine transaminase (ALT) occurred in 38%, increased aspartate aminotransferase (AST) occurred in 41%, including Grade 3 or 4 increased ALT in 3.3% and increased AST in 2.9%.
- Monitor liver function tests, including ALT, AST and bilirubin, every 2 weeks during the first month of treatment, then monthly thereafter and then as clinically indicated. Withhold and then resume at same or reduced dose upon improvement or permanently discontinue AUGTYRO based on the severity.

Myalgia with Creatine Phosphokinase (CPK) Elevation

- AUGTYRO can cause myalgia with or without creatine phosphokinase (CPK) elevation. Myalgia occurred in 13% of patients, with Grade 3 in 0.7%. Concurrent increased CPK within a 7-day window was observed in 3.7% of patients.
- Advise patients to report any unexplained muscle pain, tenderness, or weakness. Monitor serum CPK levels during AUGTYRO treatment and monitor CPK levels every 2 weeks during the first month of treatment and as needed in patients reporting unexplained muscle pain, tenderness, or weakness. Initiate supportive care as clinically indicated. Based on severity, withhold and then resume AUGTYRO at same or reduced dose upon improvement.

Hyperuricemia

- 21 patients (5%) experienced hyperuricemia reported as an adverse reaction, 0.7% experienced Grade 3 or 4 hyperuricemia. One patient without pre-existing gout required urate-lowering medication.
- Monitor serum uric acid levels prior to initiating AUGTYRO and periodically during treatment. Initiate treatment with urate-lowering medications as clinically indicated. Withhold and then resume at same or reduced dose upon improvement, or permanently discontinue AUGTYRO based on severity.

Skeletal Fractures

- Fractures occurred in 2.3% of patients and involved the ribs (0.5%), feet (0.5%), spine (0.2%), acetabulum (0.2%), sternum (0.2%), and ankles (0.2%). Some fractures occurred at sites of disease and prior radiation therapy.
- Of 26 evaluable patients in an ongoing open-label study in pediatric patients, fractures occurred in one 12-year-old patient (ankle/foot) and one 10-year-old patient (stress fracture). AUGTYRO was interrupted in both patients. AUGTYRO is not approved for use in pediatric patients less than 12 years of age.
- Promptly evaluate patients with signs or symptoms (e.g., pain, changes in mobility, deformity) of fractures. There are no data on the effects of AUGTYRO on healing of known fractures and risk of future fractures.

Embryo-Fetal Toxicity

- Based on literature reports in humans with congenital mutations leading to changes in tropomyosin receptor tyrosine kinase (TRK) signaling, findings from animal studies, and its mechanism of action, AUGTYRO can cause fetal harm when administered to a pregnant woman.
- Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective non-hormonal contraception during treatment with AUGTYRO and for 2 months following the last dose, since AUGTYRO can render some hormonal contraceptives ineffective.
- Advise male patients with female partners of reproductive potential to use effective contraception during treatment with AUGTYRO and for 4 months after the last dose.

Important Safety Information (cont'd)

Adverse Reactions

- The safety of AUGTYRO was evaluated in 426 patients in TRIDENT-1. The most common adverse reactions (≥20%) were dizziness, dysgeusia, peripheral neuropathy, constipation, dyspnea, fatigue, ataxia, cognitive impairment, muscular weakness, and nausea.

Drug Interactions

Effects of Other Drugs on AUGTYRO

- Avoid concomitant use with P-gp inhibitors, strong or moderate CYP3A inducers, and strong or moderate CYP3A inhibitors. Discontinue CYP3A inhibitors for 3 to 5 elimination half-lives of the CYP3A inhibitor prior to initiating AUGTYRO.

Effects of AUGTYRO on other Drugs

Certain CYP3A4 Substrates

- Avoid concomitant use unless otherwise recommended in the Prescribing Information for CYP3A substrates, where minimal concentration changes can cause reduced efficacy. If concomitant use is unavoidable, increase the CYP3A4 substrate dosage in accordance with approved product labeling.
- Repotrectinib is a CYP3A4 inducer. Concomitant use of repotrectinib decreases the concentration of CYP3A4 substrates, which can reduce the efficacy of these substrates.

Contraceptives

- Repotrectinib can decrease progestin or estrogen exposure to an extent that could reduce the effectiveness of hormonal contraceptives.
- Avoid concomitant use of AUGTYRO with hormonal contraceptives. Advise females of childbearing potential to use an effective nonhormonal contraceptive.

Please see enclosed U.S. Full Prescribing Information for AUGTYRO.

References

1. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Non-Small Cell Lung Cancer, V.3. 2025. © National Comprehensive Cancer Network, Inc. 2025. All rights reserved. Accessed April 3, 2025. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.
2. AUGTYRO [prescribing information]. Princeton, NJ: Bristol-Myers Squibb Company; 2024.
3. American Medical Association. ICD-10-CM Expert 2025. American Medical Association; 2024.

Bristol Myers Squibb®
Access Support®

At Bristol Myers Squibb, We Provide Support With Purpose

Patients are the reason behind what we do. BMS Access Support is dedicated to helping patients access their prescribed BMS medications. When patients are prescribed AUGTYRO and enroll in BMS Access Support, they will have access to:

Coverage Assistance

BMS Access Support may offer benefits investigations, prior authorization assistance, and appeal process support.*

Financial Support

Eligible commercially insured patients may pay as little as $0 per one-month supply.†

For patients insured through a government program or who do not have insurance, BMS Access Support can provide information regarding independent charitable foundations.‡

Educational Resources

A library of office support resources provides information about patient access, payer policy details, product distribution, coding, billing, and reimbursement. Patients also have access to educational materials to help them understand their insurance coverage.

A Free Trial Offer† may be available for patients newly prescribed AUGTYRO.

*The accurate completion of reimbursement or coverage-related documentation is the responsibility of the healthcare provider and patient. Bristol Myers Squibb and its agents make no guarantee regarding reimbursement for any service or item.

†Restrictions apply. Please see pocket for full Terms and Conditions, including complete eligibility requirements.

‡It is important to note that charitable foundations are independent from Bristol-Myers Squibb Company and have their own eligibility criteria and evaluation process. Bristol Myers Squibb cannot guarantee that a patient will receive assistance.

We're here for you.

Patient access support, reimbursement resources, and financial support options may be available through **BMS Access Support®**

Call a Patient Access Specialist at 1-800-861-0048, 8 AM to 8 PM ET, Monday–Friday

Find resources and enrollment information at www.BMSAccessSupport.com

Schedule a meeting with an Access & Reimbursement Manager via the BMS Access Support website

Please see Important Safety Information on pages 13–15 and U.S. Full Prescribing Information for AUGTYRO.

Bristol Myers Squibb®

3600-US-2500027 04/25

AUGTYRO™ (repotrectinib) 40 mg capsules