EPIC

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Instructions for running a query in the Epic® Electronic Health Record (EHR) system

These are considerations for identifying appropriate patients for folate receptor alpha (FRα) testing and mirvetuximab soravtansine-gynx treatment evaluation

INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION

Mirvetuximab soravtansine-gynx is indicated for the treatment of adult patients with folate receptor-alpha (FRα) positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens. Select patients for therapy based on an FDA-approved test.

IMPORTANT SAFETY INFORMATION

WARNING: OCULAR TOXICITY

- **Mirvetuximab soravtansine-gynx can cause severe ocular toxicities, including visual impairment, keratopathy, dry eye, photophobia, eye pain, and uveitis.**
- **Conduct an ophthalmic exam including visual acuity and slit lamp exam prior to initiation of mirvetuximab soravtansine-gynx, every other cycle for the first 8 cycles, and as clinically indicated.**
- **Administer prophylactic artificial tears and ophthalmic topical steroids.**
- **Withhold mirvetuximab soravtansine-gynx for ocular toxicities until improvement and resume at the same or reduced dose.**
- **Discontinue mirvetuximab soravtansine-gynx for Grade 4 ocular toxicities.**

FDA=US Food and Drug Administration.

Click here for full Prescribing Information including Boxed Warning.

Table of Contents

Please see two options included in this resource for running queries to identify appropriate patients for testing and treatment evaluation:

1. The **FRα Testing Instructions** allow for identification of patients with ovarian cancer who may be eligible for FRα testing
2. The **Platinum-Resistant Ovarian Cancer Treatment Evaluation Instructions** allow for identification of patients with ovarian cancer who may be eligible for treatment with mirvetuximab soravtansine-gynx

- Considerations and Limitations.....3
- Instruction Set #1: **FRα Testing**
  - EHR System Considerations 4
  - Suggested Search Criteria 8
- Instruction Set #2: **Platinum-Resistant Ovarian Cancer Treatment Evaluation**
  - EHR System Considerations 9
  - Suggested Search Criteria 14
- Indication and Important Safety Information 15

Considerations and Limitations

The Suggested Search Criteria provide health systems with guidance to identify adult patients diagnosed with ovarian cancer who meet previously defined clinical criteria.

The considerations for the Epic EHR system were designed to support clinical decision-making in platinum-resistant ovarian cancer (PROC) through identification of patients with the FRα biomarker and evaluation of treatment.

These considerations were designed specifically to use Suggested Search Criteria in the Epic EHR system and will not work for other conditions, treatments, or therapeutic areas and are not applicable for other EHR systems.

The process outlined in this piece is variable, and not all steps will apply to every health system. Any steps or settings that are not part of a health system's standard process should be excluded or modified accordingly. Any questions should be directed to the appropriate service provider. The practice is solely responsible for implementing, testing, monitoring, and ongoing operation of any EHR tools.

Notes

- The customer (ie, physician, medical group, integrated delivery network, etc.) is solely responsible for implementation, testing, and monitoring of the considerations to ensure proper orientation of its EHR system
- Capabilities, functionality, and set-up (customization) for each individual EHR system vary. AbbVie shall not be responsible for revising the implementation considerations it provides to any customer if that customer modifies or changes its software, or the configuration of its EHR system, after such time as the implementation considerations have been initially provided by AbbVie
- While AbbVie tests its implementation considerations on multiple EHR systems, the considerations are not guaranteed to work for all available EHR systems and AbbVie shall have no liability thereto
- While EHRs may assist providers in identifying appropriate patients for consideration of assessment and treatment, the decision and action should ultimately be decided by a provider in consultation with the patient, after a review of the patient's records to determine eligibility, and AbbVie shall have no liability thereto
- The considerations have not been designed to and are not tools and/or solutions for meeting Advancing Care Information and/or any other quality/accreditation requirement
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IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS

Ocular Disorders

Mirvetuximab soravtansine-gynx can cause severe ocular adverse reactions, including visual impairment, keratopathy (corneal disorders), dry eye, photophobia, eye pain, and uveitis.

Ocular adverse reactions occurred in 59% of patients with ovarian cancer treated with mirvetuximab soravtansine-gynx. Eleven percent (11%) of patients experienced Grade 3 ocular adverse reactions, including blurred vision, keratopathy (corneal disorders), dry eye, cataract, photophobia, and eye pain; two patients (0.3%) experienced Grade 4 events (keratopathy and cataract). The most common (≥5%) ocular adverse reactions were blurred vision (48%), keratopathy (36%), dry eye (27%), cataract (16%), photophobia (14%), and eye pain (10%).

The median time to onset for first ocular adverse reaction was 5.1 weeks (range: 0.1 to 68.6). Of the patients who experienced ocular events, 53% had complete resolution; 38% had partial improvement (defined as a decrease in severity by one or more grades from the worst grade at last follow up). Ocular adverse reactions led to permanent discontinuation of mirvetuximab soravtansine-gynx in 1% of patients.

Premedication and use of lubricating and ophthalmic topical steroid eye drops during treatment with mirvetuximab soravtansine-gynx are recommended. Advise patients to avoid use of contact lenses during treatment with mirvetuximab soravtansine-gynx unless directed by a healthcare provider.

Refer patients to an eye care professional for an ophthalmic exam including visual acuity and slit lamp exam prior to treatment initiation, every other cycle for the first 8 cycles, and as clinically indicated. Promptly refer patients to an eye care professional for any new or worsening ocular signs and symptoms.

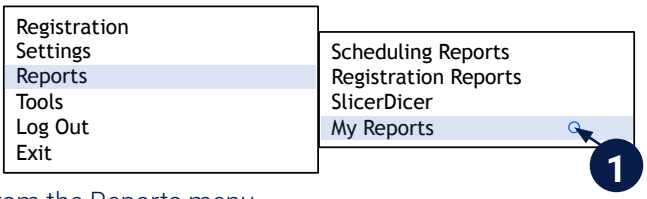
Monitor for ocular toxicity and withhold, reduce, or permanently discontinue mirvetuximab soravtansine-gynx based on severity and persistence of ocular adverse reactions.

Click here for full Prescribing Information including Boxed Warning.

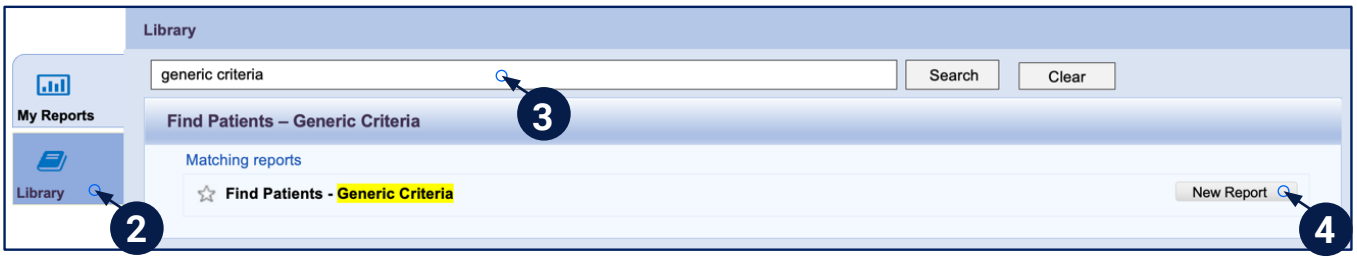
EHR SYSTEM CONSIDERATIONS: PATIENTS WITH PLATINUM-RESISTANT OVARIAN CANCER

The FRα Testing Instructions allow for identification of patients with ovarian cancer who may be eligible for FRα testing.

1. Access Reporting Workbench (click the Epic logo > Reports > My Reports)



2. Navigate to the Library tab from the Reports menu
3. Enter "generic criteria" or "find patients" in the search field and click Search
4. Select the Find Patients – Generic Criteria report and click New



IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D)

Pneumonitis

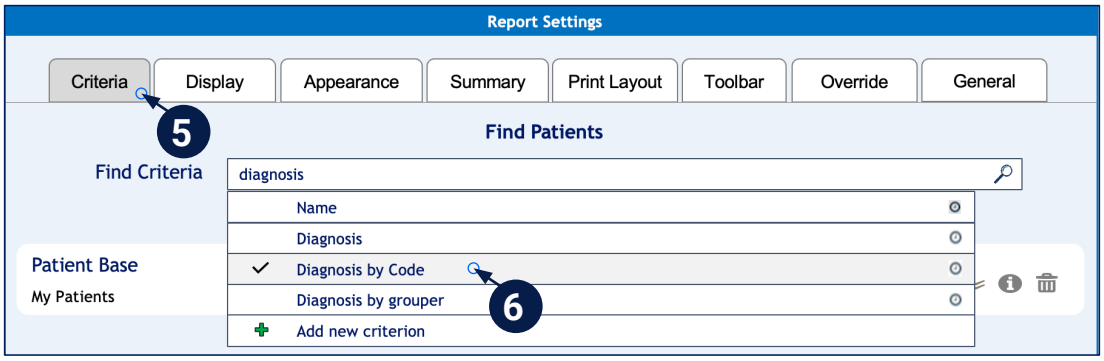
Severe, life-threatening, or fatal interstitial lung disease (ILD), including pneumonitis, can occur in patients treated with mirvetuximab soravtansine-gynx.

Pneumonitis occurred in 10% of patients treated with mirvetuximab soravtansine-gynx, including 1% with Grade 3 events and 1 patient (0.1%) with a Grade 4 event. One patient (0.1%) died due to respiratory failure in the setting of pneumonitis and lung metastases. One patient (0.1%) died due to respiratory failure of unknown etiology. Pneumonitis led to permanent discontinuation of mirvetuximab soravtansine-gynx in 3% of patients.

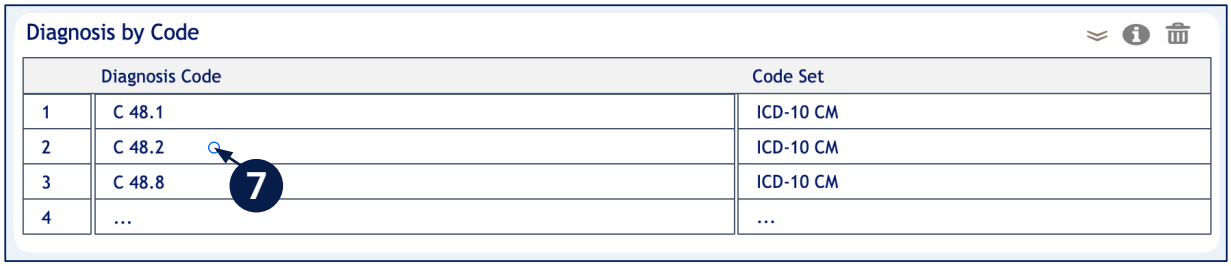
Monitor patients for pulmonary signs and symptoms of pneumonitis, which may include hypoxia, cough, dyspnea, or interstitial infiltrates on radiologic exams. Infectious, neoplastic, and other causes for such symptoms should be excluded through appropriate investigations. Withhold mirvetuximab soravtansine-gynx for patients who develop persistent or recurrent Grade 2 pneumonitis until symptoms resolve to ≤ Grade 1 and consider dose reduction. Permanently discontinue mirvetuximab soravtansine-gynx in all patients with Grade 3 or 4 pneumonitis. Patients who are asymptomatic may continue dosing of mirvetuximab soravtansine-gynx with close monitoring.

EHR SYSTEM CONSIDERATIONS: PATIENTS WITH PLATINUM-RESISTANT OVARIAN CANCER (cont'd)

5. In the Report Settings window, select the Criteria tab and add the first criterion to the query
6. In the Find Criteria field, enter "diagnosis" and select the Diagnosis by Code criterion
(note: when using groupers, select Diagnosis by Grouper and select the ovarian cancer Diagnosis Grouper)



7. Enter and select all suggested ICD-10 codes for ovarian cancer (C48.1, C48.2, C48.8, C56.1, C56.2, C56.3, C56.9, C57.00, C57.01, C57.02, C57.10, C57.11, C57.12, C57.20, C57.21, C57.22, C57.3, C57.4, C57.8)



Helpful Tip: A Diagnosis Grouper for ovarian cancer may be available. The use of groupers is an optional buy and may be considered when familiar with the grouper concept.

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D)

Peripheral Neuropathy (PN)

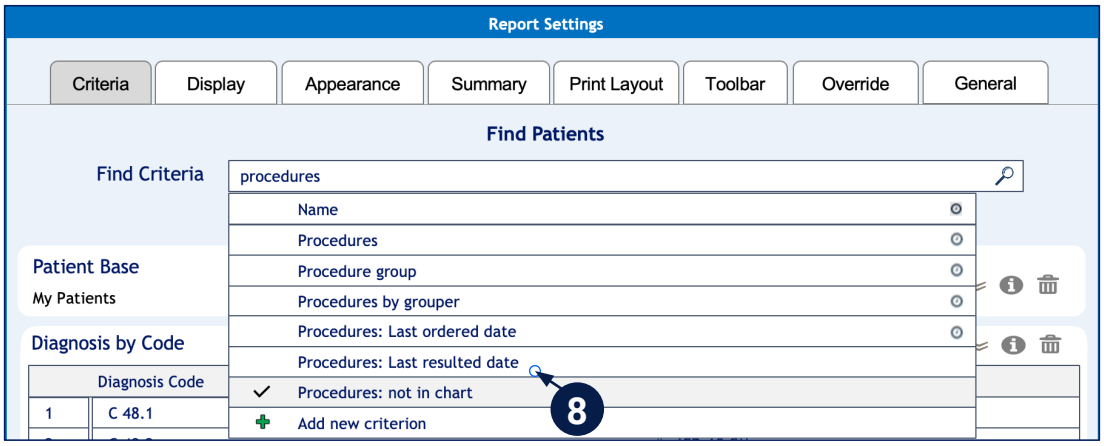
Peripheral neuropathy occurred in 36% of patients with ovarian cancer treated with mirvetuximab soravtansine-gynx across clinical trials; 3% of patients experienced Grade 3 peripheral neuropathy.

Peripheral neuropathy adverse reactions included peripheral neuropathy (20%), peripheral sensory neuropathy (9%), paraesthesia (6%), neurotoxicity (3%), hypoaesthesia (1%), peripheral motor neuropathy (0.9%), polyneuropathy (0.3%), and peripheral sensorimotor neuropathy (0.1%). Monitor patients for signs and symptoms of neuropathy, such as paresthesia, tingling or a burning sensation, neuropathic pain, muscle weakness, or dysesthesia. For patients experiencing new or worsening PN, withhold dosage, dose reduce, or permanently discontinue mirvetuximab soravtansine-gynx based on the severity of PN.

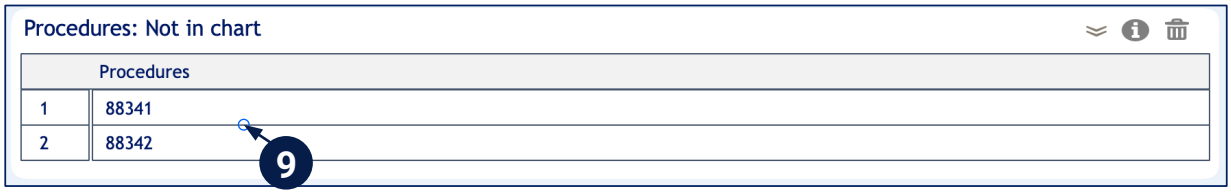
ICD-10=International Classification of Diseases, Tenth Revision.

EHR SYSTEM CONSIDERATIONS: PATIENTS WITH PLATINUM-RESISTANT OVARIAN CANCER (cont'd)

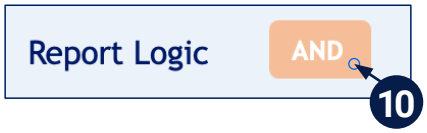
8. In the Find Criteria field, enter "procedures" and select the Procedures: Not in chart criterion



9. Enter the CPT® codes for FRα testing (88341, 88342)



10. Set the logic to include patients with any of the ovarian cancer ICD-10 codes and exclude patients with a procedure order for any of the FRα testing CPT® codes



IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D)

Embryo-Fetal Toxicity

Based on its mechanism of action, mirvetuximab soravtansine-gynx can cause embryo-fetal harm when administered to a pregnant woman because it contains a genotoxic compound (DM4) and affects actively dividing cells.

CPT®=Current Procedural Terminology.

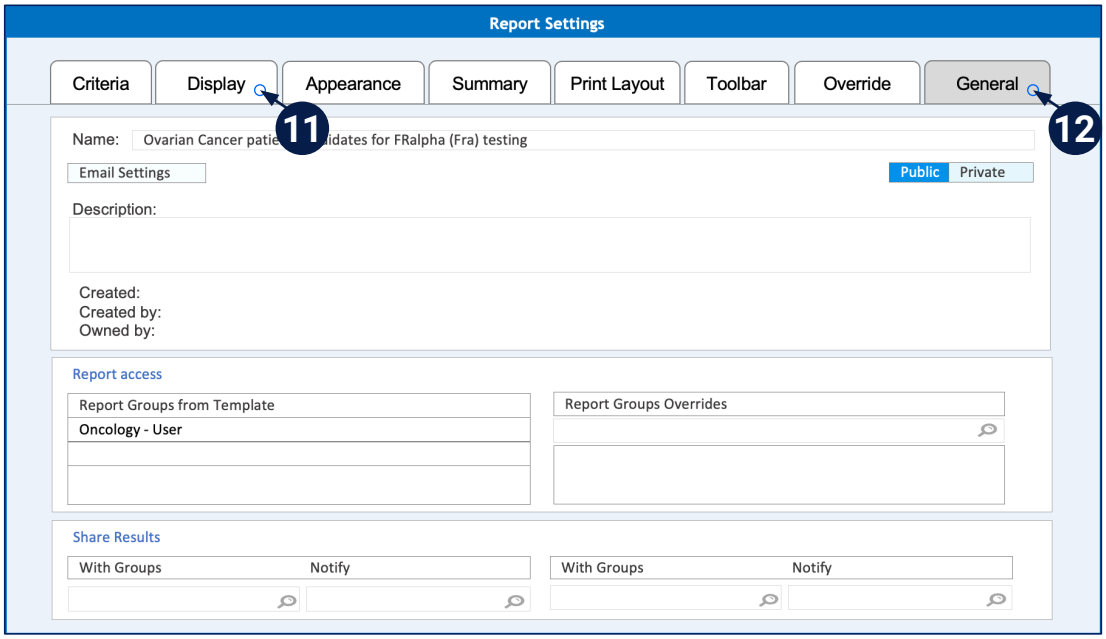
Click here for full Prescribing Information including Boxed Warning.

EHR SYSTEM CONSIDERATIONS: PATIENTS WITH PLATINUM-RESISTANT OVARIAN CANCER (cont'd)

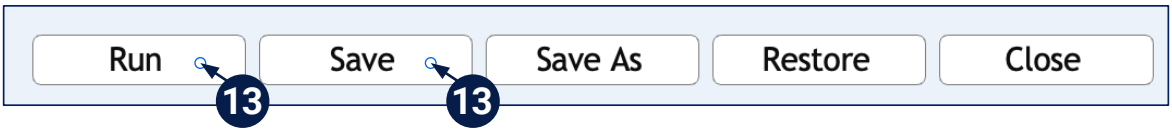
11. Select the Display tab to set all display columns for the report. Search for any display information in the Available Columns pane. Select all desired columns and click the right arrow to drag to the Selected Columns pane

- Consider adding a display column for future patient appointments. In the Available Columns window, select "Next appointment with me", "Next scheduled appointment", or another similar display column. Once the report has been run, filter or sort the display column to find patients with future appointments (for example in the next 6-8 weeks)

12. In the General tab, enter the desired Report Name and Description (for example, "*Ovarian Cancer patient candidates for FRalpha (FRα) testing*")



13. Click Save and Run to run the query. The query will display all patients matching the criteria



Helpful Tip: Consider using the Display tab or using available report filters, such as Current Medications or Date of Next Visit to further refine and sort the output of the query.

Once you complete this report, you can save it, and re-run as often as you would like. You can also apply filters to further refine your search needs.

IMPORTANT SAFETY INFORMATION (CONT'D)

ADVERSE REACTIONS

The most common (≥20 %) adverse reactions, including lab abnormalities, were increased aspartate aminotransferase, fatigue, increased alanine aminotransferase, blurred vision, nausea, increased alkaline phosphatase, diarrhea, abdominal pain, keratopathy, peripheral neuropathy, musculoskeletal pain, decreased lymphocytes, decreased platelets, decreased magnesium, decreased hemoglobin, dry eye, constipation, decreased leukocytes, vomiting, decreased albumin, decreased appetite, and decreased neutrophils.

Click here for full Prescribing Information including Boxed Warning.

SUGGESTED SEARCH CRITERIA

Patients with platinum-resistant ovarian cancer who may be candidates for FRα testing

Institutions and practices must determine whether the patient is platinum-resistant when evaluating whether mirvetuximab soravtansine-gynx is appropriate.

Include Diagnosis of Ovarian Cancer[1-3]

ICD-10 code	Description
C48.1	Malignant neoplasm of the peritoneum
C48.2	Malignant neoplasm of peritoneum, unspecified
C48.8	Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum
C56.1	Malignant neoplasm of ovary, right ovary
C56.2	Malignant neoplasm of ovary, left ovary
C56.3	Malignant neoplasm of bilateral ovaries
C56.9	Malignant neoplasm of ovary, unspecified
C57.00	Malignant neoplasm of unspecified fallopian tube
C57.01	Malignant neoplasm of right fallopian tube
C57.02	Malignant neoplasm of left fallopian tube
C57.10	Malignant neoplasm of unspecified broad ligament
C57.11	Malignant neoplasm of right broad ligament
C57.12	Malignant neoplasm of left broad ligament
C57.20	Malignant neoplasm of unspecified round ligament
C57.21	Malignant neoplasm of right round ligament
C57.22	Malignant neoplasm of left round ligament
C57.3	Malignant neoplasm of parametrium
C57.4	Malignant neoplasm of uterine adnexa, unspecified
C57.8	Malignant neoplasm of overlapping sites of female genital organs

Include platinum-based therapies and consider the following:

Prior use of bevacizumab, cisplatin, carboplatin, docetaxel, paclitaxel, pegylated liposomal doxorubicin, topotecan, oral cyclophosphamide (this may be documented in the medication list and/or list of regimens. Depending on the configuration and naming conventions of the regimens, consider a manual chart review to confirm the patient is platinum resistant).

Exclude Patients With Previous FRα Testing[4]

Procedural type	CPT® code	Description
FOLR1 IHC	88342	Immunohistochemistry or immunocytochemistry, per specimen; initial single antibody stain procedure
FOLR1 IHC	88341	Immunohistochemistry or immunocytochemistry, per specimen; each additional single antibody stain procedure (list separately in addition to code for primary procedure)

IMPORTANT SAFETY INFORMATION (CONT'D)

DRUG INTERACTIONS

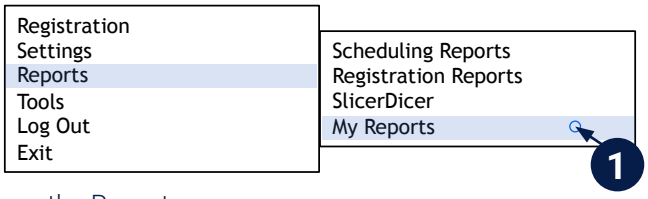
DM4 is a CYP3A4 substrate. Closely monitor patients for adverse reactions with mirvetuximab soravtansine-gynx when used concomitantly with strong CYP3A4 inhibitors.

Click here for full Prescribing Information including Boxed Warning.

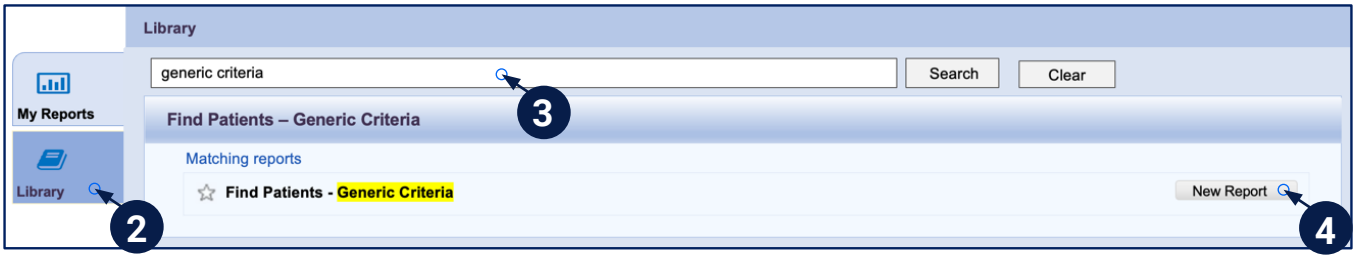
EHR SYSTEM CONSIDERATIONS: PATIENTS WITH PLATINUM-RESISTANT OVARIAN CANCER

The Platinum-Resistant Ovarian Cancer Treatment Evaluation allows for identification of patients with platinum-resistant ovarian cancer who may be eligible for treatment with mirvetuximab soravtansine-gynx.

1. Access Reporting Workbench (click the Epic logo > Reports > My Reports)



2. Navigate to the Library tab from the Reports menu
3. Enter "generic criteria" or "find patients" in the search field and click Search
4. Select the Find My Patients – Generic Criteria report and click New



IMPORTANT SAFETY INFORMATION (CONT'D)

USE IN SPECIAL POPULATIONS

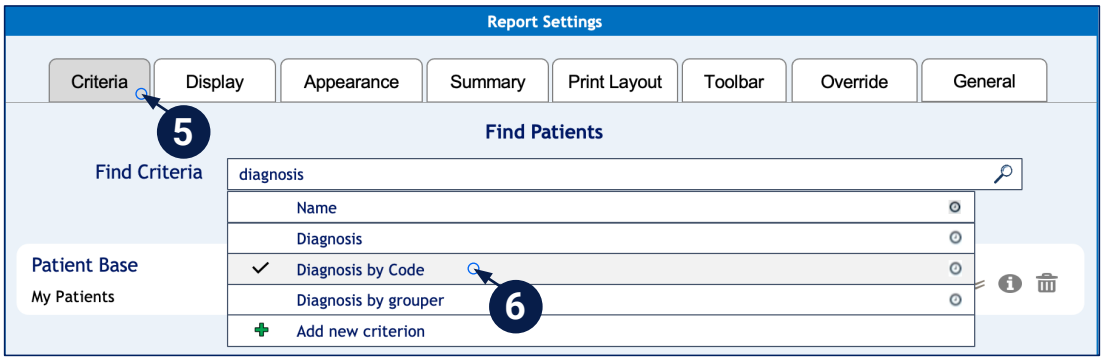
Lactation

Advise women not to breastfeed during treatment with mirvetuximab soravtansine-gynx and for 1 month after the last dose.

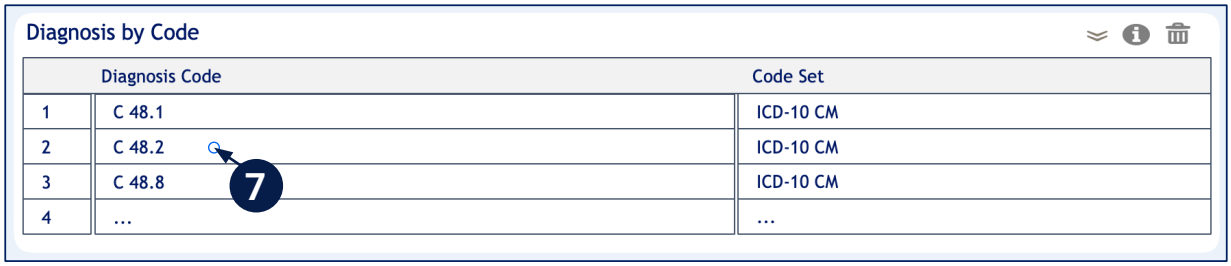
Click here for full Prescribing Information including Boxed Warning.

EHR SYSTEM CONSIDERATIONS: PATIENTS WITH PLATINUM-RESISTANT OVARIAN CANCER (cont'd)

5. In the Report Settings window, select the Criteria tab and add the first criterion to the query
6. In the Find Criteria field, enter "diagnosis" and select the Diagnosis by Code criterion (note: when using groupers, select Diagnosis by Grouper and select the ovarian cancer Diagnosis Grouper)



7. Enter and select all suggested ICD-10 codes for ovarian cancer (C48.1, C48.2, C48.8, C56.1, C56.2, C56.3, C56.9, C57.00, C57.01, C57.02, C57.10, C57.11, C57.12, C57.20, C57.21, C57.22, C57.3, C57.4, C57.8)



Helpful Tip: The use of Groupers is optional and may be considered if one is familiar with the Grouper concept. A Diagnosis Grouper for ovarian cancer and a Medication Grouper for platinum-based therapies may be available for use.

IMPORTANT SAFETY INFORMATION (CONT'D)

USE IN SPECIAL POPULATIONS (CONT'D)

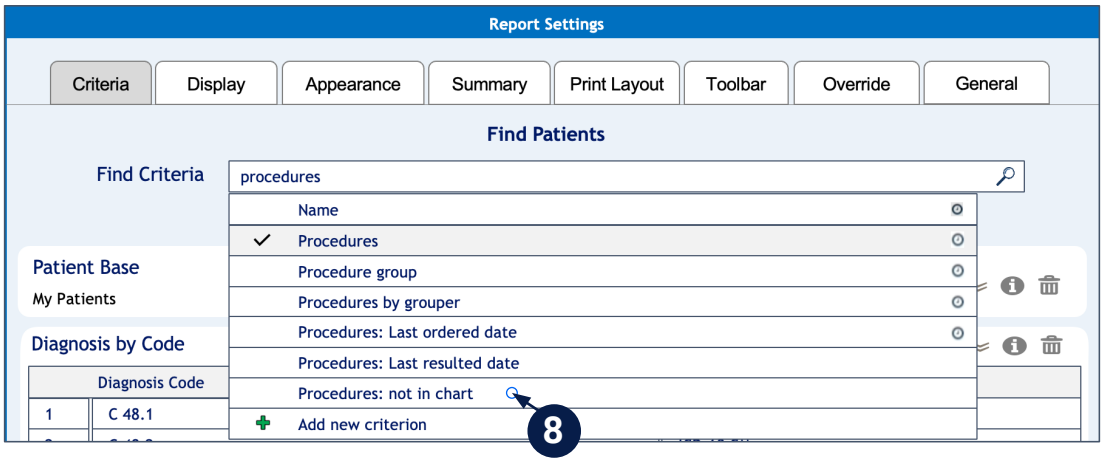
Hepatic Impairment

Avoid use of mirvetuximab soravtansine-gynx in patients with moderate or severe hepatic impairment (total bilirubin >1.5 ULN).

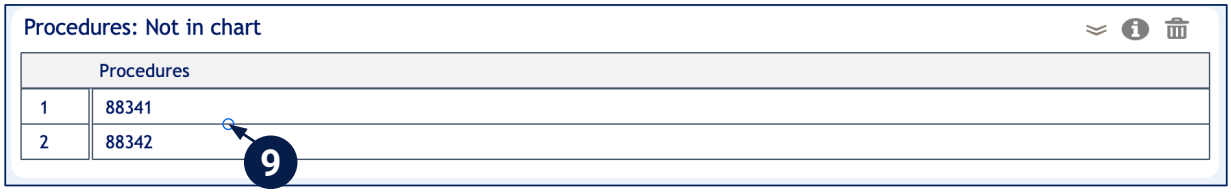
Click here for full Prescribing Information including Boxed Warning.

EHR SYSTEM CONSIDERATIONS: PATIENTS WITH PLATINUM-RESISTANT OVARIAN CANCER (cont'd)

8. In the Find Criteria field, enter "procedures" and select the Procedures criterion



9. Enter the CPT® codes for FRα testing (88341, 88342)



IMPORTANT SAFETY INFORMATION (CONT'D)

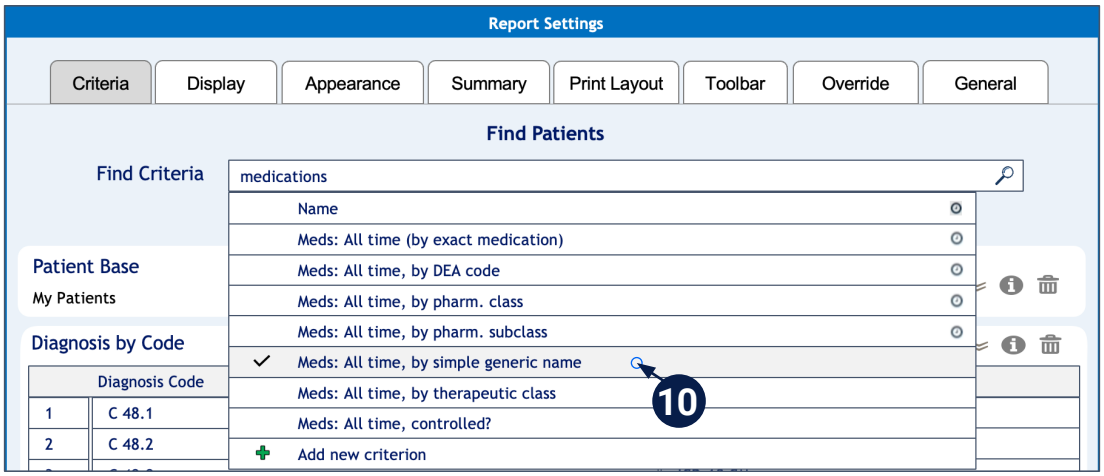
INDICATION

Mirvetuximab soravtansine-gynx is indicated for the treatment of adult patients with folate receptor-alpha (FRα) positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens. Select patients for therapy based on an FDA-approved test.

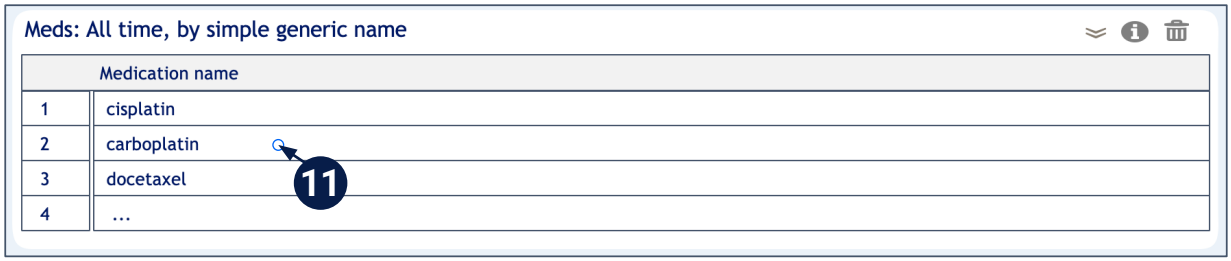
Click here for full Prescribing Information including Boxed Warning.

EHR SYSTEM CONSIDERATIONS: PATIENTS WITH PLATINUM-RESISTANT OVARIAN CANCER (cont'd)

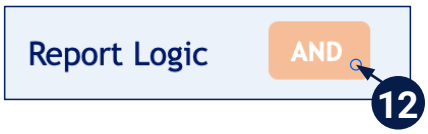
10. In the Find Criteria field, enter "medication" and select the Meds: All time, by simple generic name criterion



11. Enter and select the desired treatments (bevacizumab, cisplatin, carboplatin, docetaxel, paclitaxel, pegylated liposomal doxorubicin, topotecan, cyclophosphamide)



12. Set the logic to include patients with any of the ovarian cancer ICD-10 codes, include patients with a procedure order for any of the FRα testing CPT® codes, and include patients with ≥1 of the platinum-based treatments



IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS

Ocular Disorders

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Ocular adverse reactions occurred in 59% of patients with ovarian cancer treated with mirvetuximab soravtansine-gynx. Eleven percent (11%) of patients experienced Grade 3 ocular adverse reactions, including blurred vision, keratopathy (corneal disorders), dry eye, cataract, photophobia, and eye pain; two patients (0.3%) experienced Grade 4 events (keratopathy and cataract). The most common (≥5%) ocular adverse reactions were blurred vision (48%), keratopathy (36%), dry eye (27%), cataract (16%), photophobia (14%), and eye pain (10%).

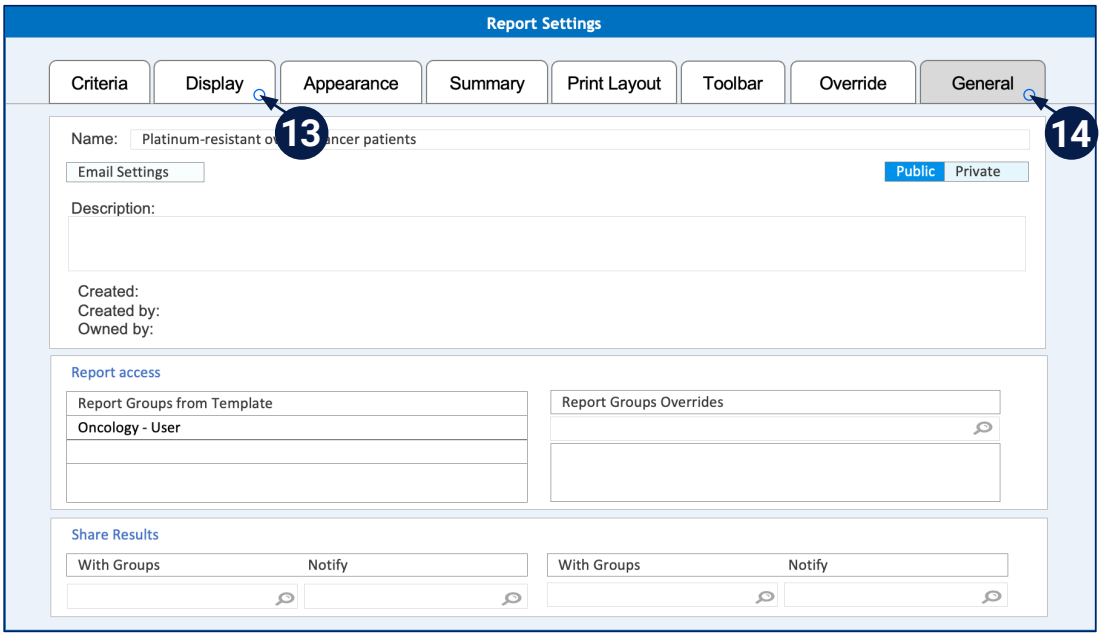
The median time to onset for first ocular adverse reaction was 5.1 weeks (range: 0.1 to 68.6). Of the patients who experienced ocular events, 53% had complete resolution; 38% had partial improvement (defined as a decrease in severity by one or more grades from the worst grade at last follow up). Ocular adverse reactions led to permanent discontinuation of mirvetuximab soravtansine-gynx in 1% of patients.

EHR SYSTEM CONSIDERATIONS: PATIENTS WITH PLATINUM-RESISTANT OVARIAN CANCER (cont'd)

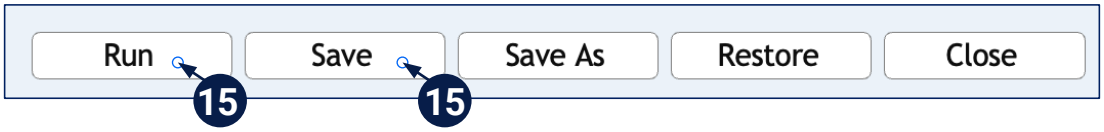
13. Select the Display tab to set all display columns for the report. Search for any display information in the Available Columns pane. Select all desired columns and click the right arrow to drag to the Selected Columns pane

- Consider adding a display column for future patient appointments. In the Available Columns window, select "Next appointment with me", "Next scheduled appointment", or another similar display column. Once the report is created, filter or sort the display column to find patients with future appointments (for example in the next 6-8 weeks)

14. In the General tab, enter the desired Report Name and Description (for example, "*Patients with platinum-resistant ovarian cancer*")



15. Click Save and Run to run the query. The query will display all patients matching the criteria



Helpful Tip: Consider using the Display tab or using available report filters, such as Current Medications or Date of Next Visit to further refine and sort the output of the query.

Once you complete this report, you can save it, and re-run as often as you would like. You can also apply filters to further refine your search needs.

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D)

Ocular Disorders (cont'd)

Premedication and use of lubricating and ophthalmic topical steroid eye drops during treatment with mirvetuximab soravtansine-gynx are recommended. Advise patients to avoid use of contact lenses during treatment with mirvetuximab soravtansine-gynx unless directed by a healthcare provider.

Refer patients to an eye care professional for an ophthalmic exam including visual acuity and slit lamp exam prior to treatment initiation, every other cycle for the first 8 cycles, and as clinically indicated. Promptly refer patients to an eye care professional for any new or worsening ocular signs and symptoms.

Monitor for ocular toxicity and withhold, reduce, or permanently discontinue mirvetuximab soravtansine-gynx based on severity and persistence of ocular adverse reactions.

Click here for full Prescribing Information including Boxed Warning.

SUGGESTED SEARCH CRITERIA

Patients with platinum-resistant ovarian cancer

Institutions and practices must determine whether the patient is platinum-resistant when evaluating whether mirvetuximab soravtansine-gynx is appropriate.

Include Diagnosis of Ovarian Cancer[1-3]

ICD-10 code	Description
C48.1	Malignant neoplasm of the peritoneum
C48.2	Malignant neoplasm of peritoneum, unspecified
C48.8	Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum
C56.1	Malignant neoplasm of ovary, right ovary
C56.2	Malignant neoplasm of ovary, left ovary
C56.3	Malignant neoplasm of bilateral ovaries
C56.9	Malignant neoplasm of ovary, unspecified
C57.00	Malignant neoplasm of unspecified fallopian tube
C57.01	Malignant neoplasm of right fallopian tube
C57.02	Malignant neoplasm of left fallopian tube
C57.10	Malignant neoplasm of unspecified broad ligament
C57.11	Malignant neoplasm of right broad ligament
C57.12	Malignant neoplasm of left broad ligament
C57.20	Malignant neoplasm of unspecified round ligament
C57.21	Malignant neoplasm of right round ligament
C57.22	Malignant neoplasm of left round ligament
C57.3	Malignant neoplasm of parametrium
C57.4	Malignant neoplasm of uterine adnexa, unspecified
C57.8	Malignant neoplasm of overlapping sites of female genital organs

Include platinum-based therapies and consider the following:

Prior use of bevacizumab, cisplatin, carboplatin, docetaxel, paclitaxel, pegylated liposomal doxorubicin, topotecan, oral cyclophosphamide (this may be documented in the medication list and/or list of regimens. Depending on the configuration and naming conventions of the regimens, consider a manual chart review to confirm the patient is platinum resistant).

Include Patients With Previous FRα Testing[4]

Procedural type	CPT® code	Description
FOLR1 IHC	88342	Immunohistochemistry or immunocytochemistry, per specimen; initial single antibody stain procedure
FOLR1 IHC	88341	Immunohistochemistry or immunocytochemistry, per specimen; each additional single antibody stain procedure (list separately in addition to code for primary procedure)

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D)

Pneumonitis

Severe, life-threatening, or fatal interstitial lung disease (ILD), including pneumonitis, can occur in patients treated with mirvetuximab soravtansine-gynx.

Click here for full Prescribing Information including Boxed Warning.

Indication and Important Safety Information

INDICATION

Mirvetuximab soravtansine-gynx is indicated for the treatment of adult patients with folate receptor-alpha (FRα) positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens. Select patients for therapy based on an FDA-approved test.

IMPORTANT SAFETY INFORMATION

WARNING: OCULAR TOXICITY

- **Mirvetuximab soravtansine-gynx can cause severe ocular toxicities, including visual impairment, keratopathy, dry eye, photophobia, eye pain, and uveitis.**
- **Conduct an ophthalmic exam including visual acuity and slit lamp exam prior to initiation of mirvetuximab soravtansine-gynx, every other cycle for the first 8 cycles, and as clinically indicated.**
- **Administer prophylactic artificial tears and ophthalmic topical steroids.**
- **Withhold mirvetuximab soravtansine-gynx for ocular toxicities until improvement and resume at the same or reduced dose.**
- **Discontinue mirvetuximab soravtansine-gynx for Grade 4 ocular toxicities.**

WARNINGS AND PRECAUTIONS

Ocular Disorders

Mirvetuximab soravtansine-gynx can cause severe ocular adverse reactions, including visual impairment, keratopathy (corneal disorders), dry eye, photophobia, eye pain, and uveitis.

Ocular adverse reactions occurred in 59% of patients with ovarian cancer treated with mirvetuximab soravtansine-gynx. Eleven percent (11%) of patients experienced Grade 3 ocular adverse reactions, including blurred vision, keratopathy (corneal disorders), dry eye, cataract, photophobia, and eye pain; two patients (0.3%) experienced Grade 4 events (keratopathy and cataract). The most common (≥5%) ocular adverse reactions were blurred vision (48%), keratopathy (36%), dry eye (27%), cataract (16%), photophobia (14%), and eye pain (10%).

The median time to onset for first ocular adverse reaction was 5.1 weeks (range: 0.1 to 68.6). Of the patients who experienced ocular events, 53% had complete resolution; 38% had partial improvement (defined as a decrease in severity by one or more grades from the worst grade at last follow up). Ocular adverse reactions led to permanent discontinuation of mirvetuximab soravtansine-gynx in 1% of patients.

Premedication and use of lubricating and ophthalmic topical steroid eye drops during treatment with mirvetuximab soravtansine-gynx are recommended. Advise patients to avoid use of contact lenses during treatment with mirvetuximab soravtansine-gynx unless directed by a healthcare provider.

Refer patients to an eye care professional for an ophthalmic exam including visual acuity and slit lamp exam prior to treatment initiation, every other cycle for the first 8 cycles, and as clinically indicated. Promptly refer patients to an eye care professional for any new or worsening ocular signs and symptoms.

Monitor for ocular toxicity and withhold, reduce, or permanently discontinue mirvetuximab soravtansine-gynx based on severity and persistence of ocular adverse reactions.

Pneumonitis

Severe, life-threatening, or fatal interstitial lung disease (ILD), including pneumonitis, can occur in patients treated with mirvetuximab soravtansine-gynx.

Pneumonitis occurred in 10% of patients treated with mirvetuximab soravtansine-gynx, including 1% with Grade 3 events and 1 patient (0.1%) with a Grade 4 event. One patient (0.1%) died due to respiratory failure in the setting of pneumonitis and lung metastases. One patient (0.1%) died due to respiratory failure of unknown etiology. Pneumonitis led to permanent discontinuation of mirvetuximab soravtansine-gynx in 3% of patients.

Monitor patients for pulmonary signs and symptoms of pneumonitis, which may include hypoxia, cough, dyspnea, or interstitial infiltrates on radiologic exams. Infectious, neoplastic, and other causes for such symptoms should be excluded through appropriate investigations. Withhold mirvetuximab soravtansine-gynx for patients who develop persistent or recurrent Grade 2 pneumonitis until symptoms resolve to ≤ Grade 1 and consider dose reduction. Permanently discontinue mirvetuximab soravtansine-gynx in all patients with Grade 3 or 4 pneumonitis. Patients who are asymptomatic may continue dosing of mirvetuximab soravtansine-gynx with close monitoring.

Indication and Important Safety Information (cont'd)

WARNINGS AND PRECAUTIONS (CONT'D)

Peripheral Neuropathy (PN)

Peripheral neuropathy occurred in 36% of patients with ovarian cancer treated with mirvetuximab soravtansine-gynx across clinical trials; 3% of patients experienced Grade 3 peripheral neuropathy. Peripheral neuropathy adverse reactions included peripheral neuropathy (20%), peripheral sensory neuropathy (9%), paraesthesia (6%), neurotoxicity (3%), hypoaesthesia (1%), peripheral motor neuropathy (0.9%), polyneuropathy (0.3%), and peripheral sensorimotor neuropathy (0.1%). Monitor patients for signs and symptoms of neuropathy, such as paresthesia, tingling or a burning sensation, neuropathic pain, muscle weakness, or dysesthesia. For patients experiencing new or worsening PN, withhold dosage, dose reduce, or permanently discontinue mirvetuximab soravtansine-gynx based on the severity of PN.

Embryo-Fetal Toxicity

Based on its mechanism of action, mirvetuximab soravtansine-gynx can cause embryo-fetal harm when administered to a pregnant woman because it contains a genotoxic compound (DM4) and affects actively dividing cells.

Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with mirvetuximab soravtansine-gynx and for 7 months after the last dose.

ADVERSE REACTIONS

The most common (≥20 %) adverse reactions, including lab abnormalities, were increased aspartate aminotransferase, fatigue, increased alanine aminotransferase, blurred vision, nausea, increased alkaline phosphatase, diarrhea, abdominal pain, keratopathy, peripheral neuropathy, musculoskeletal pain, decreased lymphocytes, decreased platelets, decreased magnesium, decreased hemoglobin, dry eye, constipation, decreased leukocytes, vomiting, decreased albumin, decreased appetite, and decreased neutrophils.

DRUG INTERACTIONS

DM4 is a CYP3A4 substrate. Closely monitor patients for adverse reactions with mirvetuximab soravtansine-gynx when used concomitantly with strong CYP3A4 inhibitors.

USE IN SPECIAL POPULATIONS

Lactation

Advise women not to breastfeed during treatment with mirvetuximab soravtansine-gynx and for 1 month after the last dose.

Hepatic Impairment

Avoid use of mirvetuximab soravtansine-gynx in patients with moderate or severe hepatic impairment (total bilirubin >1.5 ULN).

Please see full Prescribing Information, including BOXED WARNING

References: 1. Malignant neoplasm of retroperitoneum and peritoneum C48-. ICD 10 data. Accessed September 14, 2022. https://www.icd10data.com/ICD10CM/Codes/C00-D49/C45-C49/C48- **2.** Malignant neoplasm of ovary C56-. ICD 10 data. Accessed September 12, 2022. https://www.icd10data.com/ICD10CM/Codes/C00-D49/C51-C58/C56- **3.** Malignant neoplasm of other and unspecified female genital organs C57-. ICD 10 data. Accessed September 12, 2022. https://www.icd10data.com/ICD10CM/Codes/C00-D49/C51-C58/C57- **4.** Billing and coding: MolDX: immunohistochemistry (IHC) indications for breast pathology. Centers for Medicare & Medicaid Services. Updated November 11, 2020. Accessed September 12, 2022. https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=54271&ver=16

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