Access & Affordability Guide

Indication

BALVERSA® (erdafitinib) is a kinase inhibitor indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma (mUC) with susceptible *FGFR3* genetic alterations whose disease has progressed on or after at least one line of prior systemic therapy.

Select patients for therapy based on an FDA-approved companion diagnostic for BALVERSA®.

Limitations of Use

BALVERSA® is not recommended for the treatment of patients who are eligible for and have not received prior PD-1 or PD-L1 inhibitor therapy.

Information on FDA-approved tests for the detection of *FGFR3* genetic alterations in urothelial cancer is available at: https://www.fda.gov/CompanionDiagnostics.

Important Safety Information

- **Warnings and Precautions** include ocular disorders, hyperphosphatemia and soft tissue mineralization, and embryo-fetal toxicity.
- **Adverse Reactions:** In the pooled safety population described in Warnings and Precautions, the median duration of treatment was 4.8 months (range: 0.1 to 43 months). The most common (>20%) adverse reactions, including laboratory abnormalities, were increased phosphate, nail disorders, stomatitis, diarrhea, increased creatinine, increased alkaline phosphatase, increased alanine aminotransferase, decreased hemoglobin, decreased sodium, increased aspartate aminotransferase, fatigue, dry mouth, dry skin, decreased phosphate, decreased appetite, dysgeusia, constipation, increased calcium, dry eye, palmar-plantar erythrodysesthesia syndrome, increased potassium, alopecia, and central serous retinopathy.

FDA = U.S. Food and Drug Administration; FGFR = fibroblast growth factor receptor; PD-L1/PD-1 = programmed death ligand 1/ programmed cell death protein 1.

Please see Important Safety Information on pages 13-14 and click here for the full BALVERSA® Prescribing Information.

Balversa® (erdafitinib)
3, 4, 5 mg tablets

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Table of Contents

Introduction

This Access & Affordability Guide has been created to provide you with information about BALVERSA® (erdafitinib). This guide provides information about how to access BALVERSA®, coding, guidance related to payer-approval processes, and important product information to support your patients.

- This document is presented for informational purposes only and is not intended to provide reimbursement or legal advice
- Laws, regulations, and policies concerning reimbursement are complex and updated frequently
  - While we have made an effort to be current as of the issue date of this document, the information may not be as current or comprehensive when you view it
  - Similarly, all codes are supplied for informational purposes only, and this information does not represent any statement, promise, or guarantee by Janssen Biotech, Inc., about coverage, levels of reimbursement, payment, or charge
- Please consult with your payer organization(s) for local or actual coverage and reimbursement policies and with your internal reimbursement specialist for any reimbursement or billing questions

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Companion Diagnostic Test (CDx) for *FGFR3* Genetic Alterations

To identify patients eligible for BALVERSA®[1]

- Select patients for the treatment of locally advanced or metastatic urothelial carcinoma with BALVERSA® based on the presence of susceptible *FGFR3* genetic alterations in tumor specimens as detected by an FDA-approved companion diagnostic. The test detects clinically actionable *FGFR3* genetic alterations from formalin-fixed paraffin-embedded tumor tissue[2]
- The approved companion diagnostic is available in various national and regional molecular pathology testing labs
- Contact your reference laboratory to see if they can run an *FGFR3* test
- Information on FDA-approved tests for the detection of *FGFR3* genetic alterations in urothelial cancer is available at: https://www.fda.gov/CompanionDiagnostics

Important Safety Information

Warnings and Precautions

The safety population described in the Warnings and Precautions reflect a pooled safety population of 479 patients with advanced urothelial cancer and *FGFR* alterations who received BALVERSA®.

Ocular Disorders — BALVERSA® can cause ocular disorders, including central serous retinopathy/retinal pigment epithelial detachment (CSR/RPED) resulting in visual field defect.

CSR/RPED occurred in 22% of patients treated with BALVERSA®, with a median time to first onset of 46 days. In 104 patients with CSR, 40% required dose interruptions and 56% required dose reductions; 2.9% of BALVERSA®-treated patients required permanent discontinuation for CSR. Of the 24 patients who restarted BALVERSA® after dose interruption with or without dose reduction, 67% had recurrence and/or worsening of CSR after restarting. CSR was ongoing in 41% of the 104 patients at the time of last evaluation.

Dry eye symptoms occurred in 26% of BALVERSA®-treated patients. All patients should receive dry eye prophylaxis with ocular demulcents as needed.

Perform monthly ophthalmological examinations during the first 4 months of treatment and every 3 months afterwards, and urgently at any time for visual symptoms. Ophthalmological examination should include assessment of visual acuity, slit lamp examination, fundoscopy, and optical coherence tomography. Withhold or permanently discontinue BALVERSA® based on severity and/or ophthalmology exam findings.

Please see Important Safety Information on pages 13-14 and click here for the full BALVERSA® Prescribing Information.

Initiation of BALVERSA® Therapy[1]

Dosing and dose adjustments overview

For full Dosing and Dose Modification, please refer to section 2 of the full Prescribing Information.

STARTING DOSE
8 mg once daily

Check serum phosphate levels (mg/dL) 14-21 days after initiating treatment*

DOSE TITRATION

Increase dose to 9 mg once daily if serum phosphate level is <9.0 mg/dL and there are no ocular disorders or grade ≥2 adverse reactions	Maintain dose of 8 mg once daily if serum phosphate level is ≥9.0

Withhold or reduce dose as directed for any patient with adverse reactions, if needed, based on section 2 of the full Prescribing Information

DOSE MODIFICATION

1st dose reduction (two 4 mg tablets) **8 mg**	1st dose reduction (two 3 mg tablets) **6 mg**
2nd dose reduction (two 3 mg tablets) **6 mg**	2nd dose reduction (one 5 mg tablet) **5 mg**
3rd dose reduction (one 5 mg tablet) **5 mg**	3rd dose reduction (one 4 mg tablet) **4 mg**
4th dose reduction (one 4 mg tablet) **4 mg**	4th dose reduction **STOP**
5th dose reduction **STOP**	

*The recommended starting dose of BALVERSA® is 8 mg (two 4 mg tablets) orally once daily, with a dose increase to 9 mg (three 3 mg tablets) once daily based on tolerability, including hyperphosphatemia, at 14 to 21 days. Swallow tablets whole with or without food. If vomiting occurs any time after taking BALVERSA®, the next dose should be taken the next day. Treatment should continue until disease progression or unacceptable toxicity occurs.

If a dose of BALVERSA® is missed, it can be taken as soon as possible on the same day. Resume the regular daily dose schedule for BALVERSA® the next day. Extra tablets should not be taken to make up for the missed dose.

No fasting restrictions. Tablets can be taken with or without food

Tablets should be swallowed whole

A missed dose should be taken as soon as possible on the same day and the regular daily dose taken on the next day; extra tablets should not be taken to make up for the missed dose

Important Safety Information (cont'd)

Hyperphosphatemia and Soft Tissue Mineralization — BALVERSA® can cause hyperphosphatemia leading to soft tissue mineralization, cutaneous calcinosis, non-uremic calciphylaxis and vascular calcification. Increases in phosphate levels are a pharmacodynamic effect of BALVERSA®. Increased phosphate occurred in 73% of BALVERSA®-treated patients. The median onset time of increased phosphate was 16 days (range: 8–421) after initiating BALVERSA®. Twenty-four percent of patients received phosphate binders during treatment with BALVERSA®. Vascular calcification was observed in 0.2% of patients treated with BALVERSA®.

Initiation of BALVERSA® Therapy[1] (cont'd)

Dose increase based on serum phosphate levels

- Advise patients to avoid concomitant use with agents that can alter serum phosphate levels during this initial phosphate-assessment period
- Increase the dose of BALVERSA® to 9 mg once daily if serum phosphate level is <9.0 mg/dL and there are no ocular disorders or Grade 2 or greater adverse reactions

Managing eye disorders

- Provide referral for monthly ophthalmological exams during the first 4 months of treatment and every 3 months afterwards, and urgently at any time for visual symptoms
  - Examination should include assessment of visual acuity, slit lamp examination, fundoscopy, and optical coherence tomography
  - To prevent or treat dry eyes, advise patients to use artificial tear substitutes, hydrating or lubricating eye gels or ointments frequently, at least every 2 hours during waking hours

To **find a doctor**, go to: **www.aoa.org**

- Click on "Find a Doctor"
- Type in your ZIP Code and click "search"

Managing hyperphosphatemia

- Increases in phosphate levels are a pharmacodynamic effect of BALVERSA®
- Monitor for hyperphosphatemia throughout treatment
- In all patients, restrict phosphate intake to 600-800 mg daily and avoid concomitant use of agents that may increase serum phosphate levels
- If serum phosphate is above 7.0 mg/dL, consider adding an oral phosphate binder until serum phosphate level returns to <7.0 mg/dL
- Monitor phosphate levels monthly for hyperphosphatemia and withhold, dose reduce, or permanently discontinue BALVERSA® based on duration and severity of hyperphosphatemia

Advise patients about the risk of embryo-fetal toxicity

Advise pregnant patients and females of reproductive potential of the potential risk of the fetus. Advise females to inform their healthcare providers of a known or suspected pregnancy. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with BALVERSA® and for 1 month after the last dose.

Lactation

Advise females not to breastfeed during treatment with BALVERSA® and for one month after the last dose.

Infertility

Advise females of reproductive potential that BALVERSA® may impair fertility.

Drug interactions

Advise patients to inform their healthcare providers of all concomitant medications, including prescription medicines, over-the-counter drugs, and herbal products.

Skin, mucous or nail disorders

Advise patients to contact their healthcare provider if they experience progressive or intolerable skin, mucous or nail disorders.

Important Safety Information (cont'd)

Hyperphosphatemia and Soft Tissue Mineralization (cont´d) — Monitor for hyperphosphatemia throughout treatment. In all patients, restrict phosphate intake to 600-800 mg daily and avoid concomitant use of agents that may increase serum phosphate levels. If serum phosphate is above 7.0 mg/dL, consider adding an oral phosphate binder until serum phosphate level returns to <7.0 mg/dL. Withhold, dose reduce, or permanently discontinue BALVERSA® based on duration and severity of hyperphosphatemia.

Accessing BALVERSA®

BALVERSA® is restricted to the following Specialty Distributors and Specialty Pharmacy

Specialty Distributors	Phone	Fax	Email	Website
ASD Healthcare®	1-800-746-6273	1-800-547-9413	service@asdhealthcare.com	ASDHealthcare.com
Oncology Supply®	1-800-633-7555	1-800-248-8205	service@oncologysupply.com	OncologySupply.com

Some Specialty Pharmacies, such as those at the Veterans Health Administration or Integrated Health Systems, may have access to BALVERSA® through an authorized Specialty Distributor. Please contact ASD Healthcare® or Oncology Supply® for inquiries.

Renewals and new prescriptions can be called in to CVS Specialty® by phone, or sent by fax or to ePrescribe

Specialty Pharmacy	Phone	Fax	Website
CVS Specialty®	1-855-539-4712	1-888-435-1256	CVSSpecialty.com

New prescriptions can be called in to **CVS Specialty®** by phone (1.855.539.4712) or faxed (1.888.435.1256), or patients can visit **CVSSpecialty.com** and click on Get Started. ePrescribe is available through **CVS Specialty®**, 800 Biermann Ct, Suite B, Mt Prospect, IL 60056. Patients can also drop a specialty prescription off at any CVS Pharmacy location. It will be transferred to **CVS Specialty®** and a member of the CVS Specialty® CareTeam will contact the patient.

CVS Specialty® hours of operation: 8:00 AM–8:00 PM ET, Monday–Friday.

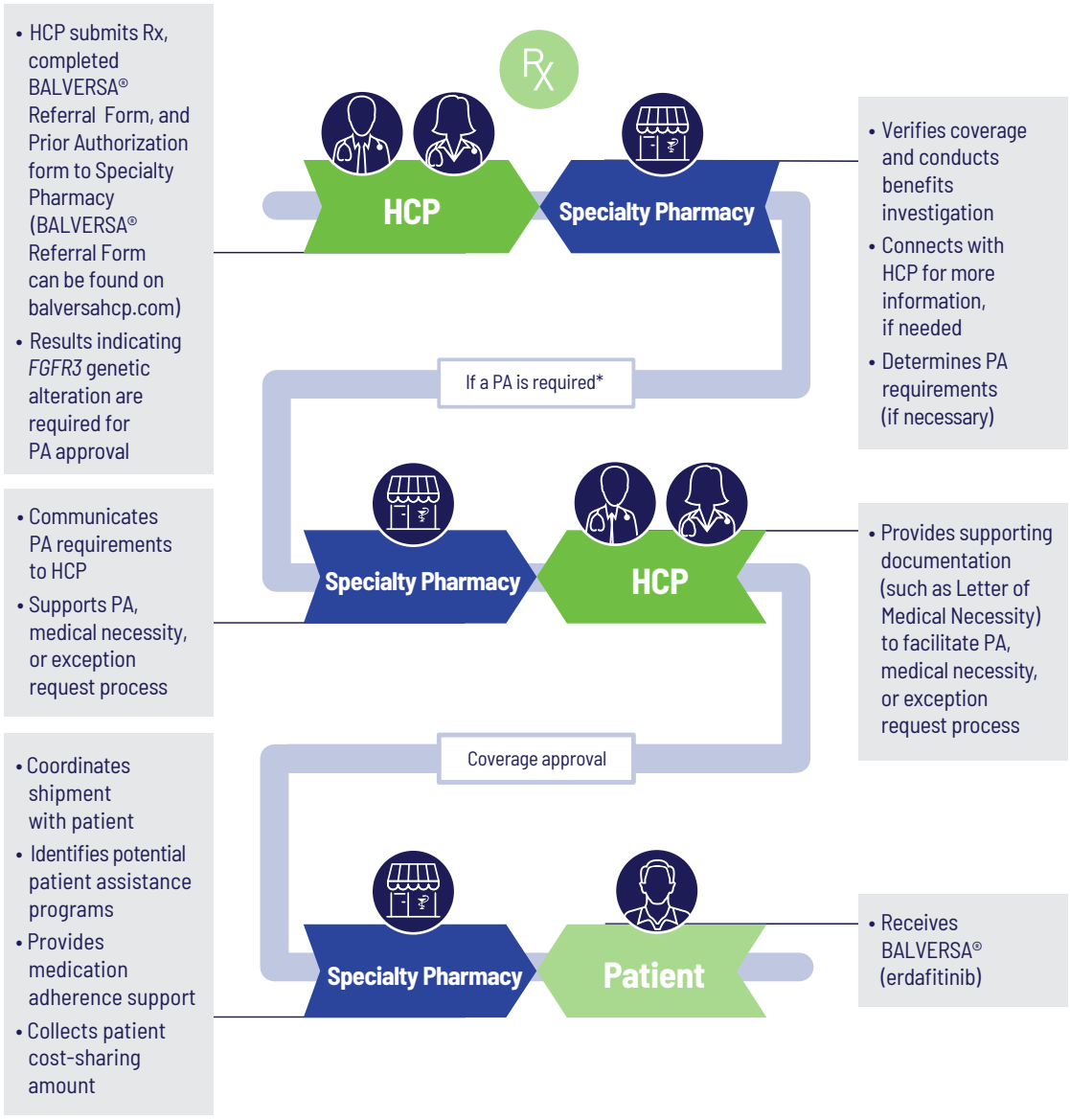
Additional Resources for BALVERSA®

- **Sample Exception Letter**
  Each payer follows a different process when filing exceptions and appeals. Submit an exception letter when requesting an exception for BALVERSA®.
- **Sample Letter of Medical Necessity**
  Submit a letter to support the medical necessity of treatment with BALVERSA® either with the initial claim or when requesting reconsideration of a denied claim.

Important Safety Information (cont'd)

Embryo-Fetal Toxicity – Based on the mechanism of action and findings in animal reproduction studies, BALVERSA® can cause fetal harm when administered to a pregnant female. In a rat embryo-fetal toxicity study, erdafitinib caused malformations and embryo-fetal death at maternal exposures that were less than the human exposures at the maximum human recommended dose based on AUC. Advise pregnant patients of the potential risk to the fetus. Advise female patients of reproductive potential to use effective contraception during treatment with BALVERSA® and for one month after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with BALVERSA® and for one month after the last dose.

Example of Specialty Pharmacy Process



HCP = healthcare professional; PA = prior authorization.

*Also supports exception request process when applicable. If a PA submission or exception request is denied, an appeal can be filed to request that the payer reconsider the initial decision. Either the provider or the patient can initiate an appeal.

Important Safety Information (cont'd)

Adverse Reactions

In the pooled safety population described in Warnings and Precautions, the median duration of treatment was 4.8 months (range: 0.1 to 43 months). The most common (>20%) adverse reactions, including laboratory abnormalities, were increased phosphate, nail disorders, stomatitis, diarrhea, increased creatinine, increased alkaline phosphatase, increased alanine aminotransferase, decreased hemoglobin, decreased sodium, increased aspartate aminotransferase, fatigue, dry mouth, dry skin, decreased phosphate, decreased appetite, dysgeusia, constipation, increased calcium, dry eye, palmar-plantar erythrodysesthesia syndrome, increased potassium, alopecia, and central serous retinopathy.

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Balversa® (erdafitinib)
3, 4, 5 mg tablets

Coding

ICD-10-CM

ICD-10-CM codes represent the patient's diagnosis and are used by healthcare providers, pharmacies, and payers to support appropriateness of the requested treatment.

ICD-10-CM Code[3]	Diagnosis
C67.0	Malignant neoplasm of trigone of bladder
C67.1	Malignant neoplasm of dome of bladder
C67.2	Malignant neoplasm of lateral wall of bladder
C67.3	Malignant neoplasm of anterior wall of bladder
C67.4	Malignant neoplasm of posterior wall of bladder
C67.5	Malignant neoplasm of bladder neck
C67.6	Malignant neoplasm of ureteric orifice
C67.7	Malignant neoplasm of urachus
C67.8	Malignant neoplasm of overlapping sites of bladder
C67.9	Malignant neoplasm of bladder, unspecified

ICD-10-CM = *International Classification of Diseases, 10th Revision, Clinical Modification.*

These codes are not intended to be promotional, or to encourage or suggest a use of drug that is inconsistent with FDA-approved use. Please refer to the current policy for the latest codes, since these codes are subject to change. The codes provided are not intended to be exhaustive and may require a higher level of specificity.

Please consult your ICD-10-CM codebook for additional information.

Important Safety Information (cont'd)

Adverse Reactions (cont'd)

In Cohort 1 of the BLC3001 (NCT03390504, THOR) study:

- Serious adverse reactions occurred in 41% of patients who received BALVERSA®. Serious reactions in >2% of patients included urinary tract infection (4.4%), hematuria (3.7%), hyponatremia (2.2%), and acute kidney injury (2.2%). Fatal adverse reactions occurred in 4.4% of patients who received BALVERSA®, including sudden death (1.5%), pneumonia (1.5%), renal failure (0.7%), and cardiorespiratory arrest (0.7%).
- Permanent discontinuation of BALVERSA® due to an adverse reaction occurred in 14% of patients. Adverse reactions which resulted in permanent discontinuation of BALVERSA® in >2% of patients included nail disorders (3%) and eye disorders (2.2%).
- Dosage interruptions of BALVERSA® due to an adverse reaction occurred in 72% of patients. Adverse reactions which required dosage interruption in >4% of patients included nail disorders (22%), stomatitis (19%), eye disorders (16%), palmar-plantar erythrodysesthesia syndrome (15%), diarrhea (10%), hyperphosphatemia (7%), increased aspartate aminotransferase (6%), and increased alanine aminotransferase (5%).
- Dose reductions of BALVERSA® due to an adverse reaction occurred in 69% of patients. Adverse reactions which required dose reductions in >4% of patients included nail disorders (27%), stomatitis (19%), eye disorders (17%), palmar-plantar erythrodysesthesia syndrome (12%), diarrhea (7%), dry mouth (4.4%), and hyperphosphatemia (4.4%).
- Clinically relevant adverse reactions in <15% of patients who received BALVERSA® included nausea (15%), pyrexia (15%), epistaxis (13%), vomiting (10%), and arthralgia (10%).

Coding (cont'd)

NDC

An NDC (National Drug Code) number is often necessary when filing a claim for reimbursement.

Dose[4]	Quantity (per bottle)	10-Digit NDC Number[4]	11-Digit NDC Number
3 mg	56	59676-030-56	59676-0030-56
3 mg	84	59676-030-84	59676-0030-84
4 mg	28	59676-040-28	59676-0040-28
4 mg	56	59676-040-56	59676-0040-56
5 mg	28	59676-050-28	59676-0050-28

Important Safety Information (cont'd)

Drug Interactions

Effects of Other Drugs on BALVERSA®

- Moderate CYP2C9 or Strong CYP3A4 Inhibitors: Consider alternative agents; however, if co-administration is unavoidable, monitor closely for adverse reactions.
- Strong CYP3A4 inducers: Avoid co-administration with BALVERSA®.
- Moderate CYP3A4 inducers: If co-administration is required at the start of BALVERSA® treatment, administer BALVERSA® at a dose of 9 mg daily.
- Serum phosphate level-altering agents: Avoid co-administration with agents that can alter serum phosphate levels before the initial dose increase period based on serum phosphate levels.

Effect of BALVERSA® on Other Drugs

- P-gp substrates: If co-administration is unavoidable, separate BALVERSA® administration by at least 6 hours before or after administration of P-gp substrates with narrow therapeutic indices.

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Support and Resources General Overview

Patient Support for BALVERSA® (erdafitinib)

BALVERSA® is dispensed by a specialty pharmacy.

Specialty pharmacies are equipped to facilitate product fulfillment and patient support. Specialty pharmacies may offer services to verify insurance coverage, identify potential patient assistance programs, and provide additional information to patients to increase adherence.

Access Support

To get your patients started on BALVERSA®, the following resources may be helpful:

- Supporting Appropriate Payer Coverage Decisions
  This brochure has been developed to help healthcare providers understand how to work with payers for coverage of medically necessary drug therapies
- Extra Help with Prescription Drug Costs: Medicare Low-Income Subsidy (LIS) Overview
  Learn about extra help available to low-income residents of the United States who are enrolled in Medicare Prescription Drug Plans
- Know Your State Interactive Tool
  This interactive tool provides information on affordability options for patients at the state level
- Sample Exception Letter
  Each payer follows a different process when filing exceptions and appeals. Submit an exception letter when requesting an exception for BALVERSA®
- Sample Letter of Medical Necessity
  Submit a letter to support the medical necessity of treatment with BALVERSA®, either with the initial claim or when requesting reconsideration of a denied claim
- Prior Authorization Considerations Checklist
  Learn more about general prior authorization processes, including items and information that may be requested from your patient's insurer
- Appeal Considerations Checklist
  If your patient's insurer denies coverage for your patient, learn more about general insurance appeals processes
- Exception Considerations Checklist
  General information on exception processes for your patient's coverage of medically necessary drug therapies

Affordability Support

Affordability Options for Prescription Drugs

This summary presents resources that may assist patients with their prescription drug costs based on their primary insurance status.

Support for patients using commercial or private health insurance to pay for BALVERSA®

The Janssen CarePath Savings Program may help eligible patients receive instant savings on their out-of-pocket medication costs for BALVERSA®. Depending on their health insurance plan, savings may apply toward co-pay, co-insurance, or deductible. Your eligible patients will pay $5 per fill. Maximum program benefit per calendar year shall apply. Not valid for patients using Medicare, Medicaid, or other government-funded programs to pay for their medications. Terms expire at the end of each calendar year and may change. Offer subject to change or end without notice. Restrictions, including monthly maximums, may apply. There is no income requirement. See program requirements at **Balversa.JanssenCarePathSavings.com**.

Providers can check patients' eligibility and enroll them in the Janssen CarePath Savings Program for BALVERSA® at **JanssenCarePathPortal.com/express**. There is a "Print a Card" feature to provide the patient with a card.

Your patients and their caregivers can enroll the patient in the Janssen CarePath Savings Program for BALVERSA® at **MyJanssenCarePath.com/express**.

Support for patients using government-funded healthcare programs or patients without insurance coverage

Patients without commercial or private health insurance may find help from the programs and resources found on **JanssenCarePath.com/Balversa**.

If you need help, call 866-378-1910, Monday through Friday, 8:00 AM to 8:00 PM ET.

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3, 4, 5 mg tablets

Please click here for the full BALVERSA® Prescribing Information.

Important Safety Information (cont'd)

Adverse Reactions (cont'd)

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- Moderate CYP3A4 inducers: If co-administration is required at the start of BALVERSA® treatment, administer BALVERSA® at a dose of 9 mg daily.
- Serum phosphate level-altering agents: Avoid co-administration with agents that can alter serum phosphate levels before the initial dose increase period based on serum phosphate levels.

Effect of BALVERSA® on Other Drugs

- P-gp substrates: If co-administration is unavoidable, separate BALVERSA® administration by at least 6 hours before or after administration of P-gp substrates with narrow therapeutic indices.

Please click here to see full BALVERSA® Prescribing Information.

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Appendix

Some payers and other formulary decision makers may require that treating physicians complete a Letter of Medical Necessity or request a formulary exception before patients can receive a specific therapy. We have provided a sample Letter of Medical Necessity and a sample Letter of Exception.*
Editable templates that you can use to create your own letters are available below.

Sample Letter of Medical Necessity

[Insert Physician Letterhead]

[Insert Name of Medical Director]
[Insert Payer Name]
[Insert Address]
[Insert City, State ZIP]

Re: Member Name: [Insert Member Name]
Member Number: [Insert Member Number]
Group Number: [Insert Group Number]

REQUEST: Authorization for treatment with BALVERSA® (erdafitinib)
DIAGNOSIS: [Insert Diagnosis] [Insert ICD]
DOSAGE FORM AND STRENGTH: [Insert Dosage Form & Strength]
REQUEST TYPE: ☐ Standard ☐ EXPEDITED

Dear [Insert Name of Medical Director or name of individual responsible for prior authorization],

I am writing to support my request for an **authorization** for the above-mentioned patient to receive treatment with BALVERSA® for [Insert indication]. My request is supported by the following:

Summary of Patient's Diagnosis

[Insert patient's diagnosis, date of diagnosis, lab results and date, current condition]

Summary of Patient's History

[Insert:

- Previous therapies/procedures, including dose and duration, response to those interventions
- Description of patient's recent symptoms/condition
- Site of medical service—include site type (eg, inpatient, hospital outpatient, outpatient clinic, private practice, or other) and rationale (eg, compliance or closely monitoring patients)
- Rationale for not using drugs that are on the plan's formulary
- Summary of your professional opinion of the patient's likely prognosis or disease progression without treatment with BALVERSA®

Note: Exercise your medical judgment and discretion when providing a diagnosis and characterization of the patient's medical condition.]

Rationale for Treatment

[Insert summary statement for rationale for treatment such as: Considering the patient's history, condition, and the full Prescribing Information supporting uses of BALVERSA®, I believe treatment with BALVERSA® at this time is medically necessary, and should be a covered and reimbursed service.]

[You may consider including documents that provide additional clinical information to support the recommendation for BALVERSA® for this patient, such as the full Prescribing Information, peer-reviewed journal articles, or clinical guidelines.]

[Given the urgent nature of this request,] please provide a timely authorization. Contact my office at [Insert Phone Number] if I can provide you with any additional information.

Sincerely,
[Insert Healthcare Provider's Name and Participating Provider Number]

Enclosures [Include full Prescribing Information and the additional support noted above]

SAMPLE

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*PLEASE NOTE: These are sample letters. Use of these letters does not guarantee reimbursement.

Appendix

Editable templates that you can use to create your own letters are available below.

Sample Letter of Exception

[Insert Physician Letterhead]

[Insert Name of Medical Director]
[Insert Payer Name]
[Insert Address]
[Insert City, State ZIP]

Re: Member Name: [Insert Member Name]
Member Number: [Insert Member Number]
Group Number: [Insert Group Number]

REQUEST: Authorization for treatment with BALVERSA® (erdafitinib)
DIAGNOSIS: [Insert Diagnosis] [Insert ICD]
DOSAGE FORM AND STRENGTH: [Insert Dosage Form & Strength]
REQUEST TYPE: ☐ Standard ☐ EXPEDITED

Dear [Insert Name of Medical Director],

I am writing to request a **formulary exception** for the above-mentioned patient to receive treatment with BALVERSA® for [Insert Indication]. My request is supported by the following:

Summary of Patient's Diagnosis

[Insert patient's diagnosis, date of diagnosis, lab results and date, current condition]

Summary of Patient's History

[Insert:

- Previous therapies/procedures, including dose and duration, response to those interventions
- Description of patient's recent symptoms/condition
- Site of medical service—include site type: inpatient, hospital outpatient, outpatient clinic, private practice, or other
- Rationale for not using drugs that are on the plan's formulary
- Summary of your professional opinion of the patient's likely prognosis or disease progression without treatment with BALVERSA®

Note: Exercise your medical judgment and discretion when providing a diagnosis and characterization of the patient's medical condition.]

SAMPLE

Rationale for Treatment

[Insert summary statement for rationale for treatment such as: Considering the patient's history, condition, and the full Prescribing Information supporting uses of BALVERSA®, I believe treatment with BALVERSA® at this time is medically necessary and should be a covered and reimbursed service.]

[You may consider including documents that provide additional clinical information to support the recommendation for BALVERSA® for this patient, such as the full Prescribing Information, peer-reviewed journal articles, or clinical guidelines.]

[Given the urgent nature of this request,] please provide a timely authorization. Contact my office at [Insert Phone Number] if I can provide you with any additional information.

Sincerely,
[Insert Healthcare Provider's Name and Participating Provider Number]

Enclosures [Include full Prescribing Information and the additional support noted above]

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*PLEASE NOTE: These are sample letters. Use of these letters does not guarantee reimbursement.

Affordability Options for Prescription Drugs

This summary presents resources that may assist patients with their prescription drug costs based on their primary insurance status.

If You Have:	These Resources May Be Available							
	Qualified Medicare Beneficiary Program (QMB)	Medicare Low-Income Subsidy ("Extra Help")	Manufacturer's Co-pay Assistance Programs	Exception Request	State Pharmaceutical Assistance Programs (SPAPs)	Drug Discount Cards	Independent Charitable Organizations	Insurance Options*
Medicare Part B	✔					**May be used instead of your insurance**	✔	• *Add a Medigap Plan*
Medicare Part D		✔		✔	✔		✔	• *Switch Part D Plans*
Medicare Advantage with Prescription Drug Plan (MA-PD)		✔		✔	✔		✔	• *Switch to Original Medicare –Add a Part D Plan –Add a Medigap Plan*
Medicaid							✔	
Medicare + Medicaid (dual eligible)		✔					✔	
Commercial Insurance			✔	✔			✔	
TRICARE (military retiree benefits)				✔			✔	
No Insurance					✔	✔	✔	• *Qualify for Medicaid* • *Purchase Insurance Plan (commercial, exchange, etc.)*

*The ability to enroll/disenroll and switch between types of Medicare coverage and Medigap plans is limited to the annual open enrollment periods, unless specific circumstances qualify a beneficiary for a Special Enrollment Period (SEP).[5] Medicaid eligibility criteria vary by state.

This document is presented for informational purposes only and is not intended to provide reimbursement or legal advice. Laws, regulations, and policies concerning reimbursement are complex and are updated frequently. While we have made an effort to be current, the information may not be as current or comprehensive when you view it. In addition, this information does not represent any statement, promise, or guarantee by Johnson & Johnson Health Care Systems Inc., or its affiliates, about coverage, levels of reimbursement, payment, or charge. Please consult with your payer organization(s) for local or actual coverage and reimbursement policies and determination processes. Please consult with your counsel or reimbursement specialist for any reimbursement or billing questions specific to your institution.

Affordability Options for Prescription Drugs (cont'd)

GLOSSARY

Drug Discount Cards: Discount drug cards provide discounts off the purchase price of certain medications and may be used by people who are uninsured or choose not to use their insurance. Not all medications are included, and the amount of discount varies. Some discount cards are free, and others must be purchased. The cards are offered by state governments, drug companies, non-profit organizations, and for-profit businesses.

Exception Request: Under most prescription drug benefit programs, a beneficiary, or a provider on the beneficiary's behalf, may request a coverage determination regarding his or her drug benefits, including the amount that a payer requires a patient to pay for a prescription drug. Policies and specific processes may vary **by plan.**

Independent Charitable Organizations: As used in this resource, "independent charitable organizations" are those organizations and programs that offer assistance with prescription out-of-pocket costs to insured individuals, including those whose prescriptions are paid, in whole or part, by any state or federally funded programs such as Medicare, Medicaid, Medigap, VA, the Department of Defense (DOD), TRICARE, or State Pharmaceutical Assistance Programs (SPAPs). This classification differs from Manufacturer's Co-Pay Assistance Programs (see below), which are specifically prohibited from use with state or federally funded programs.

Manufacturer's Co-pay Assistance Programs: Some pharmaceutical manufacturers offer assistance with out-of-pocket costs for the drugs they sell. Support may include savings on private insurance co-pay, co-insurance, or deductible for medication costs. These programs are available to people using commercial or private health insurance for their medication. Examples of commercial or private insurance are commercial insurance from a former/current employer (for the patient or their spouse, partner, or a family member), government employee health insurance, or insurance the patient buys privately or through the Health Insurance Marketplace (Healthcare.gov). These programs are not for people who use any state or federal government-funded healthcare program. Examples of these programs are Medicare, Medicaid, TRICARE, Department of Defense, and Veterans Administration.

Medicare Low-Income Subsidy (LIS): LIS is a Medicare program to help people with limited income and resources pay Medicare prescription drug costs. This program is also called "Extra Help". Those who qualify can receive help paying the drug plan premium, deductible, co-insurance, and co-payments, and have no gap in coverage.[6]

Medigap (Medicare Supplement Insurance): Medigap policies, sold by private insurance companies, help pay for some of the healthcare costs that original Medicare (Medicare Parts A and B) does not cover, including co-payments, co-insurance, and deductibles. Medigap does not cover costs associated with Medicare Part D or Medicare Advantage (Medicare Part C).[7]

Qualified Medicare Beneficiary (QMB): The QMB program is one of the Medicare savings programs available to low-income Medicare beneficiaries who meet the eligibility criteria. QMB helps pay for Part A and/or Part B premiums, deductibles, co-insurance, and co-payments, and thus may help with the out-of-pocket costs associated with Medicare Part B drugs.[8]

State Pharmaceutical Assistance Programs (SPAPs): States can offer help paying drug plan premiums and/or other drug costs. Eligibility may be based on financial need, age, or medical condition. Benefits may vary between programs.[9]

Balversa®
(erdafitinib)
3, 4, 5 mg tablets

References:
1. BALVERSA® (erdafitinib) [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. **2.** Qiagen. therascreen FGFR RGQ RT-PCR Kit instructions for use (handbook). Accessed January 24, 2024. https://www.accessdata.fda.gov/cdrh_docs/pdf18/P180043C.pdf **3.** Centers for Disease Control and Prevention. National Center for Health Statistics ICD-10-CM Browser. Accessed January 24, 2024. https://icd10cmtool.cdc.gov/ **4.** National Drug Codes List. Accessed January 24, 2024. https://ndclist.com/labeler/janssen-products-lp **5.** Centers for Medicare and Medicaid Services. Special enrollment periods. Accessed January 24, 2024. https://www.medicare.gov/basics/get-started-with-medicare/get-more-coverage/joining-a-plan/special-enrollment-periods **6.** Centers for Medicare & Medicaid Services. Medicare Prescription Drug Manual, Chapter 13. Premium and cost-sharing subsidies for low-income individuals. Revised October 1, 2018. Accessed January 24, 2024. https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter-13-Premium-and-Cost-Sharing-Subsidies-for-Low-Income-Individuals-v09-14-2018.pdf **7.** Centers for Medicare & Medicaid Services. What's Medicare Supplement Insurance (Medigap)? Accessed January 24, 2024. https://www.medicare.gov/supplement-other-insurance/medigap/whats-medigap.html **8.** Centers for Medicare & Medicaid Services. Medicare savings programs. Accessed January 24, 2024. https://www.medicare.gov/your-medicare-costs/get-help-paying-costs/medicare-savings-programs#collapse-2625 **9.** Centers for Medicare & Medicaid Services. State pharmaceutical assistance programs. Accessed January 24, 2024. https://www.medicare.gov/pharmaceutical-assistance-program/state-programs.aspx

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Please see Important Safety Information on pages 13-14 and click here for the full BALVERSA® Prescribing Information.