VENCLEXTA PATIENT SUPPORT PROGRAMS

Actor portrayals

Indications

VENCLEXTA is indicated:

- For the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).
- In combination with azacitidine, or decitabine, or low-dose cytarabine for the treatment of newly diagnosed acute myeloid leukemia (AML) in adults:
  - 75 years or older, or
  - who have comorbidities that preclude use of intensive induction chemotherapy.

Select Important Safety Information

- Concomitant use of VENCLEXTA with *strong* CYP3A inhibitors at initiation and during ramp-up is contraindicated in patients with CLL/SLL due to the potential for increased risk of tumor lysis syndrome (TLS).
- Tumor lysis syndrome, including fatal events and renal failure requiring dialysis, has occurred in patients treated with VENCLEXTA. The risk of TLS is a continuum based on multiple factors, particularly reduced renal function, tumor burden, and type of malignancy. Assess all patients for risk and provide appropriate prophylaxis for TLS, including hydration and anti-hyperuricemics. Monitor blood chemistries and manage abnormalities promptly. Employ more intensive measures (IV hydration, frequent monitoring, hospitalization) as overall risk increases. Interrupt dosing if needed; when restarting VENCLEXTA follow dose modification guidance in the Prescribing Information.
- Concomitant use of VENCLEXTA with P-gp inhibitors or strong or moderate CYP3A inhibitors increases venetoclax exposure, which may increase the risk of TLS at initiation and during ramp-up phase, and requires VENCLEXTA dose reduction.
- Grade 3 or 4 neutropenia occurred in patients treated with VENCLEXTA. Monitor blood counts and for signs of infection; manage as medically appropriate.
- In patients with AML, baseline neutrophil counts worsened in 95% to 100% of patients treated with VENCLEXTA in combination with azacitidine or decitabine or low-dose cytarabine. Neutropenia can recur with subsequent cycles.
- Fatal and serious infections such as pneumonia and sepsis have occurred in patients with VENCLEXTA. Monitor patients for signs and symptoms of infection and treat promptly. Withhold VENCLEXTA for Grade 3 and 4 infection until resolution.
- Do not administer live attenuated vaccines prior to, during, or after treatment until B-cell recovery occurs.
- VENCLEXTA may cause embryo-fetal harm. Advise females of reproductive potential to use effective contraception during treatment and for 30 days after the last dose.

Please see additional Important Safety Information on pages 13–15.

Please see the full Prescribing Information.

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VENCLEXTA®
venetoclax tablets 10mg, 50mg, 100mg

WELCOME

Genentech and AbbVie are committed to helping patients access VENCLEXTA. The programs described in this brochure are intended to support patients who have been prescribed VENCLEXTA, regardless of their situation.

TABLE OF CONTENTS

SUPPORTING PATIENTS WHO HAVE BEEN PRESCRIBED VENCLEXTA

Serious illnesses can come with many challenges. Getting VENCLEXTA shouldn't be one of them.

We believe every person should get the VENCLEXTA they have been prescribed, and we offer programs to help make this happen.

If your patients:

Need help understanding their health insurance coverage and related financial responsibilities, **VENCLEXTA Access Solutions** is here to help.

Do not have health insurance coverage or have financial concerns and meet certain eligibility criteria, the **Genentech Patient Foundation*** may be able to provide free medicine.

Have health insurance and need help paying for their medicine, **Affordability Options** may be available:

- The Genentech Oncology Co-pay Assistance Program†
- Referrals to independent co-pay assistance foundations‡

The Genentech Patient Resource Center can help answer questions and connect you to the right Genentech patient support service. Call (877) GENENTECH / (877-436-3683) to get started.

*To be eligible for free VENCLEXTA from the Genentech Patient Foundation, insured patients who have coverage for their medicine should try to pursue other forms of financial assistance, if available, and meet certain income requirements. Uninsured patients and insured patients without coverage for their medicine must meet a different set of income requirements. Genentech reserves the right to modify or discontinue the program at any time and to verify the accuracy of information submitted.

†Eligibility criteria apply. Not valid for patients using federal or state government programs to pay for their medicine and/or administration of their Genentech medicine. Patients must be taking the Genentech medicine for an FDA-approved indication. Please visit the Co-pay Program website for the full list of Terms and Conditions.

‡Independent co-pay assistance foundations have their own rules for eligibility. Genentech and AbbVie have no involvement or influence in independent foundation decision-making or eligibility criteria and do not know if a foundation will be able to help your patient. We can only refer your patient to a foundation that supports their disease state. Genentech and AbbVie do not endorse or show preference for any particular foundation. The foundations to which we refer your patient may not be the only ones that might be able to help.

Please see Important Safety Information on pages 13–15.
Please see the full Prescribing Information.

VENCLEXTA ACCESS SOLUTIONS

VENCLEXTA Access Solutions provides helpful access and reimbursement support to assist your patients and practice.

We can help your patients and practice by providing:

- **Benefits investigations (BIs)**
- **Sample billing and coding information**
- **Prior authorization (PA) resources**
- **Resources for denials and appeals**
- **Information about authorized specialty pharmacies (SPs) and specialty distributors (SDs)**
- **Referrals to financial assistance options**

To get started, submit the completed **Prescriber Service Form** and **Patient Consent Form**. These forms can be downloaded at **Genentech-Access.com/VENCLEXTA**.

To learn more about our programs and services, visit **Genentech-Access.com/VENCLEXTA** or call **(866) 422-2377**.

Please see Important Safety Information on pages 13–15.
Please see the full Prescribing Information.

VENCLEXTA® venetoclax tablets 10mg, 50mg, 100mg

VENCLEXTA SURESTART® PROGRAM

If your patient faces a coverage delay, the VENCLEXTA SureStart Program can help your patient start his or her VENCLEXTA therapy while waiting for a coverage decision.

ELIGIBILITY CRITERIA*	
Eligible	**Not eligible**
• Prescribed VENCLEXTA tablets for a labeled indication • There is a delay in prior authorization or coverage decision for VENCLEXTA	• Uninsured

HOW IT WORKS
• Shipments begin after there has been a delay in coverage decision for VENCLEXTA • Shipments can continue for up to 56 days for clinically appropriate patients if a coverage decision is still pending • Once coverage has been determined, the patient no longer qualifies for the VENCLEXTA SureStart Program

*Subject to eligibility requirements and terms and conditions. This program is void where prohibited by law and may not be used in or by residents of restricted states, if applicable.

To get started, submit the completed Prescriber Service Form and Patient Consent Form to Access Solutions. These forms can be downloaded at Genentech-Access.com/VENCLEXTA.

All FDA-approved Genentech Oncology products or combinations are eligible for the Genentech Oncology Co-pay Assistance Program. Please go to CopayAssistanceNow.com for a current list of approved products.

Please see Important Safety Information on pages 13–15.
Please see the full Prescribing Information.

VENCLEXTA® venetoclax tablets 10mg, 50mg, 100mg

GENENTECH PATIENT FOUNDATION

ELIGIBILITY CRITERIA*

Uninsured patients

With incomes under $150,000

OR

Insured patients without coverage for a Genentech medicine

With incomes under $150,000

OR

Insured patients with coverage for a Genentech medicine†

- With unaffordable out-of-pocket costs
- With household size and income within the guidelines listed below

HOUSEHOLD SIZE	ANNUAL INCOME
1	• Less than $75,000
2	• Less than $100,000
3	• Less than $125,000
4	• Less than $150,000

*For all patient types, add $25,000 for each extra person in households larger than 4 people.

†We encourage insured patients to pursue other financial assistance options prior to applying for help from the Genentech Patient Foundation, if possible.

Genentech reserves the right to modify or discontinue the program at any time and to verify the accuracy of information submitted.

To get started, submit the completed Prescriber Service Form and have your patient submit/fill out the Patient Consent Form. These forms can be downloaded at Genentech-Access.com/VENCLEXTA.

Please see Important Safety Information on pages 13–15.

Please see the full Prescribing Information.

THE GENENTECH ONCOLOGY CO-PAY ASSISTANCE PROGRAM

The Genentech Oncology Co-pay Assistance Program provides financial assistance to eligible commercially insured patients to help with their co-pays, co-insurance, or other out-of-pocket costs.

PATIENTS ARE ELIGIBLE IF THEY:

- Have commercial (private or non-governmental) insurance. This includes plans available through state and federal health insurance exchanges
- Are **not** a government beneficiary and/or participant in a federal or state-funded health insurance program (eg, Medicare, Medicare Advantage, Medigap, Medicaid, VA, DoD, TRICARE)
- Are 18 years of age or older, or have a legal guardian 18 years of age or older to manage the program
- Live in and receive treatment in the United States or U.S. Territories
- Have been prescribed VENCLEXTA for an FDA-approved indication
- Have not been prescribed VENCLEXTA in the past
- Do **not** receive support from the Genentech Patient Foundation or any independent co-pay assistance foundations

HOW IT WORKS

- Pay as little as $0 for your prescribed VENCLEXTA prescriptions and refills
- No income requirements
- The program provides up to $25,000 per 12-month benefit period
- No physical card needed; patients simply need their ID code
- Patient benefits will reset every 12 months as long as eligibility criteria continue to be met

The Co-pay Program is valid ONLY for patients with commercial (private or non-governmental) insurance who have a valid prescription for a Food and Drug Administration (FDA)-approved indication of a Genentech medicine. Patients using Medicare, Medicaid or any other federal or state government program (collectively, "Government Programs") to pay for their Genentech medicine are not eligible.

Under the Program, the patient may pay a co-pay. The final amount owed by a patient may be as little as $0 for the Genentech medicine (see Program specific details). The total patient out-of-pocket cost is dependent on the patient's health insurance plan. The Program assists with the cost of the Genentech medicine only. It does not assist with the cost of other medicines, procedures or office visit fees. After reaching the maximum annual Program benefit amount, the patient will be responsible for all remaining out-of-pocket expenses. The Program benefit amount cannot exceed the patient's out-of-pocket expenses for the cost associated with the Genentech medicine.

All participants are responsible for reporting the receipt of all Program benefits as required by any insurer or by law. The Program is only valid in the United States and U.S. Territories, is void where prohibited by law and shall follow state restrictions in relation to AB-rated generic equivalents (eg, MA, CA) where applicable. No party may seek reimbursement for all or any part of the benefit received through the Program. The Program is intended for the patient. Only the patient using the Program may receive the funds made available through the Program. The Program is not intended for third parties who reduce the amount available to the patient or take a portion for their own purposes. Patients with health plans that redirect Genentech Program assistance intended for patient out-of-pocket costs may be subject to alternate Program benefit structures. Genentech reserves the right to rescind, revoke or amend the Program without notice at any time.

Additional terms and conditions apply. Please visit the Co-pay Program website for the full list of Terms and Conditions.

VA=US Department of Veterans Affairs; DoD=US Department of Defense; U.S.=United States; ID=identification; MA=Massachusetts; CA=California.

Please see Important Safety Information on pages 13–15.
Please see the full Prescribing Information.

REFERRALS TO INDEPENDENT CO-PAY ASSISTANCE FOUNDATIONS*

If eligible publicly or commercially insured patients have difficulty paying for their co-pay, co-insurance, or other out-of-pocket costs, VENCLEXTA Access Solutions can refer them to an independent co-pay assistance foundation supporting their diagnosis.

Key points to remember about independent co-pay assistance foundation referrals:

- Eligibility requirements, all aspects of the application process, turnaround times, and the type or amount of assistance available (if any) offered can vary by foundation
- If the patient is denied assistance by one co-pay assistance foundation, they can be referred to a different foundation, if one is available
- Patients referred for co-pay assistance need not be enrolled in VENCLEXTA Access Solutions and can simply call for a referral
- Patients can call the foundation directly to request assistance

Visit Genentech-Access.com for a list of potential independent co-pay assistance foundations.

*Independent co-pay assistance foundations have their own rules for eligibility. Genentech and AbbVie have no involvement or influence in independent foundation decision-making or eligibility criteria and do not know if a foundation will be able to help your patient. We can only refer your patient to a foundation that supports their disease state. Genentech and AbbVie do not endorse or show preference for any particular foundation. The foundations to which we refer your patient may not be the only ones that might be able to help.

If you want to enroll your patients in the Genentech Oncology Co-pay Assistance Program or have any questions, call (855) MY-COPAY / (855) 692-6729 from 9 AM to 8 PM ET, Monday through Friday, or visit CopayAssistanceNow.com.

HOW VENCLEXTA IS SUPPLIED

To order any of the following for your patients, please contact one of the SPs or SDs listed on page 12.

STANDARD SUPPLY OF VENCLEXTA IN CLL/SLL	
STARTING PACK	**The starter pack provides the first 4 weeks of VENCLEXTA according to the ramp-up schedule.** **NDC #** 0074-0579-28
BOTTLE	**The recommended daily dose of 400 mg is supplied as 100 mg tablets (qty 120).** **NDC #** 0074-0576-22 **Quantity:** 120 x 100 mg tablets

STANDARD SUPPLY OF VENCLEXTA IN AML		
UNIT DOSES	**100 mg unit doses provide an option for VENCLEXTA ramp-up according to the ramp-up schedule (Days 1–3).** **NDC #** 0074-0576-11 **Quantity:** 1 x 100 mg tablet	
	VENCLEXTA + azacitidine or decitabine	**VENCLEXTA + low-dose cytarabine**
BOTTLE	**Option for ramp-up and/or recommended daily dose at 400 mg** **NDC #** 0074-0576-22 **Quantity:** 120 x 100 mg tablets	**Option for ramp-up and/or recommended daily dose at 600 mg** **NDC #** 0074-0576-30 **Quantity:** 28 x 100 mg tablets

CLL=chronic lymphocytic leukemia; SLL=small lymphocytic lymphoma; NDC=National Drug Code; qty=quantity; AML=acute myeloid leukemia.

Starting pack (for CLL/SLL only)

NDC # 0074-0579-28

10 mg and 50 mg wallets are available if dose holds should occur

10 mg wallet (14 × 10 mg tablets): **NDC #** 0074-0561-14

50 mg wallet (7 × 50 mg tablets): **NDC #** 0074-0566-07

Unit doses

10 mg unit dose (× 2): **NDC #** 0074-0561-11

50 mg unit dose: **NDC #** 0074-0566-11

100 mg unit dose: **NDC #** 0074-0576-11

Tablet bottles

100 mg bottle (qty 120): **NDC #** 0074-0576-22

100 mg bottle (qty 28): **NDC #** 0074-0576-30

Please see Important Safety Information on pages 13–15.

Please see the full Prescribing Information.

SPECIALTY PHARMACIES AND DISTRIBUTORS

The following network of SPs and SDs are authorized to dispense VENCLEXTA. This network will assist providers and patients in obtaining VENCLEXTA.

SPs may be able to provide services such as prior authorization assistance and identification of co-pay support options for eligible patients.

	Name	Phone	Fax	Website
Distributors for authorized specialty pharmacies, physicians' offices, and hospitals (pharmacy dispensed)	Cencora/Amerisource Bergen Specialty Distribution	800-746-6273	800-547-9413	asdhealthcare.com
	Cardinal Health Specialty Pharmaceutical Distribution	855-855-0708	614-553-6301	specialtyonline.cardinalhealth.com
	McKesson Plasma and Biologics (MPB)	877-625-2566	888-752-7626	connect.mckesson.com
	McKesson Specialty Health	800-482-6700	800-289-9285	mscs.mckesson.com
	Cencora/Oncology Supply	800-633-7555	800-248-8205	oncologysupply.com
Specialty Pharmacies	Biologics by McKesson	800-850-4306 Option 1	800-823-4506	biologics.mckesson.com
	Onco360 Oncology Pharmacy	877-662-6633	877-662-6355	onco360.com
	Optum Specialty fka: Avella & Diplomat	877-445-6874	877-342-4596	specialty.optumrx.com
Distributors for closed system/ federal accounts	Cencora/Amerisource Bergen Specialty Distribution	800-746-6273	800-547-9413	asdhealthcare.com
	Cardinal Health Specialty Pharmaceutical Distribution	855-855-0708	614-553-6301	specialtyonline.cardinalhealth.com
	McKesson Plasma and Biologics (MPB)	877-625-2566	888-752-7626	connect.mckesson.com
Authorized Distributors for Puerto Rico	Alivia Specialty, LLC	888-925-1989 787-925-1999	787-925-1015 787-723-6987	www.aliviahealth.com/specialty
	Cardinal Health Puerto Rico	787-625-4100	787-625-4398	www.cardinalhealth.pr
	Special Care Pharmacy Services, LLC	787-781-4585 877-899-8997 888-727-1727	787-783-2951 855-230-9963	www.specialcarepr.com

These lists are subject to change; for the most up-to-date information, please visit venclextahcp.com.

Genentech and AbbVie do not influence or advocate the use of any one specialty distributor or specialty pharmacy. We make no representation or guarantee of service or coverage of any item.

Please see Important Safety Information on pages 13–15.

Please see the full Prescribing Information.

INDICATIONS AND IMPORTANT SAFETY INFORMATION

Indications

VENCLEXTA is indicated:

- For the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).
- In combination with azacitidine, or decitabine, or low-dose cytarabine for the treatment of newly diagnosed acute myeloid leukemia (AML) in adults:
  - 75 years or older, or
  - who have comorbidities that preclude use of intensive induction chemotherapy.

Important Safety Information

Contraindication

- Concomitant use of VENCLEXTA with *strong* CYP3A inhibitors at initiation and during ramp-up phase is contraindicated in patients with CLL/SLL due to the potential for increased risk of tumor lysis syndrome (TLS).

Tumor Lysis Syndrome

- Tumor lysis syndrome, including fatal events and renal failure requiring dialysis, has occurred in patients treated with VENCLEXTA.
- VENCLEXTA can cause rapid reduction in tumor and thus poses a risk for TLS at initiation and during the ramp-up phase in all patients, and during reinitiation after dosage interruption in patients with CLL/SLL. Changes in blood chemistries consistent with TLS that require prompt management can occur as early as 6 to 8 hours following the first dose of VENCLEXTA and at each dose increase. TLS, including fatal cases, has been reported after a single 20 mg dose.
- In patients with CLL/SLL who followed the current (5 week) dose ramp-up and the TLS prophylaxis and monitoring measures, the rate of TLS was 2% in the VENCLEXTA CLL/SLL monotherapy trials. The rate of TLS remained consistent with VENCLEXTA in combination with obinutuzumab or rituximab. With a 2- to 3-week dose ramp-up and higher starting dose in patients with CLL/SLL, the TLS rate was 13% and included deaths and renal failure.
- In patients with AML who followed the current 3-day ramp-up dosing schedule and the TLS prophylaxis and monitoring measures, the rate of TLS was 1.1% in patients who received VENCLEXTA in combination with azacitidine. In patients with AML who followed a 4-day ramp-up dosing schedule and the TLS prophylaxis and monitoring measures, the rate of TLS was 5.6% and included deaths and renal failure in patients who received VENCLEXTA in combination with low-dose cytarabine.
- The risk of TLS is a continuum based on multiple factors, particularly reduced renal function, tumor burden, and type of malignancy. Splenomegaly may also increase the risk of TLS in patients with CLL/SLL.
- Assess all patients for risk and provide appropriate prophylaxis for TLS, including hydration and anti-hyperuricemics. Monitor blood chemistries and manage abnormalities promptly. Employ more intensive measures (IV hydration, frequent monitoring, hospitalization) as overall risk increases. Interrupt dosing if needed; when restarting VENCLEXTA follow dose modification guidance in the Prescribing Information.
- Concomitant use of VENCLEXTA with P-gp inhibitors or strong or moderate CYP3A inhibitors increases venetoclax exposure, which may increase the risk of TLS at initiation and during the ramp-up phase, and requires VENCLEXTA dose reduction.

Please see additional Important Safety Information on pages 14–15.
Please see the full Prescribing Information.

IMPORTANT SAFETY INFORMATION (cont'd)

Neutropenia

- In patients with CLL, Grade 3 or 4 neutropenia developed in 63% to 64% of patients and Grade 4 neutropenia developed in 31% to 33% of patients treated with VENCLEXTA in combination and monotherapy studies. Febrile neutropenia occurred in 4% to 6% of patients.
- In patients with AML, baseline neutrophil counts worsened in 95% to 100% of patients treated with VENCLEXTA in combination with azacitidine or decitabine or low-dose cytarabine. Neutropenia can recur with subsequent cycles.
- Monitor complete blood counts. Interrupt dosing for severe neutropenia. In CLL, resume at same or reduced dose. In AML, resume at same dose then reduce duration based on remission status and first or subsequent occurrence of neutropenia. Consider supportive measures including antimicrobials and growth factors (e.g., G-CSF).

Infections

- Fatal and serious infections such as pneumonia and sepsis have occurred in patients treated with VENCLEXTA. Monitor patients for signs and symptoms of infection and treat promptly. Withhold VENCLEXTA for Grade 3 and 4 infection until resolution and resume at same or reduced dose.

Immunization

- Do not administer live attenuated vaccines prior to, during, or after treatment with VENCLEXTA until B-cell recovery occurs. Advise patients that vaccinations may be less effective.

Embryo-Fetal Toxicity

- VENCLEXTA may cause embryo-fetal harm when administered to a pregnant woman. Advise females of reproductive potential to use effective contraception during treatment and for 30 days after the last dose.

Increased Mortality in Patients with Multiple Myeloma when VENCLEXTA is Added to Bortezomib and Dexamethasone

- In a randomized trial (BELLINI; NCT02755597) in patients with relapsed or refractory multiple myeloma, the addition of VENCLEXTA to bortezomib plus dexamethasone, a use for which VENCLEXTA is not indicated, resulted in increased mortality. Treatment of patients with multiple myeloma with VENCLEXTA in combination with bortezomib plus dexamethasone is not recommended outside of controlled clinical trials.

Adverse Reactions

- **In patients with CLL receiving combination therapy with obinutuzumab,** serious adverse reactions were most often due to febrile neutropenia and pneumonia (5% each). The most common adverse reactions (≥20%) of any grade were neutropenia (60%), diarrhea (28%), and fatigue (21%). Fatal adverse reactions that occurred in the absence of disease progression and with onset within 28 days of the last study treatment were reported in 2% (4/212) of patients, most often from infection.
- **In patients with CLL receiving combination therapy with rituximab,** the most frequent serious adverse reaction (≥5%) was pneumonia (9%). The most common adverse reactions (≥20%) of any grade were neutropenia (65%), diarrhea (40%), upper respiratory tract infection (39%), fatigue (22%), and nausea (21%). Fatal adverse reactions that occurred in the absence of disease progression and within 30 days of the last VENCLEXTA treatment and/or 90 days of the last rituximab were reported in 2% (4/194) of patients.
- **In patients with CLL/SLL receiving monotherapy,** the most frequent serious adverse reactions (≥5%) were pneumonia (9%), febrile neutropenia (5%), and sepsis (5%). The most common adverse reactions (≥20%) of any grade were neutropenia (50%), diarrhea (43%), nausea (42%), upper respiratory tract infection (36%), anemia (33%), fatigue (32%), thrombocytopenia (29%), musculoskeletal pain (29%), edema (22%), and cough (22%). Fatal adverse reactions that occurred in the absence of disease progression and within 30 days of venetoclax treatment were reported in 2% of patients in the VENCLEXTA monotherapy studies, most often (2 patients) from septic shock.

Please see additional Important Safety Information on pages 13 and 15.
Please see the full Prescribing Information.

- **In patients with AML receiving combination therapy with azacitidine,** the most frequent serious adverse reactions (≥5%) were febrile neutropenia (30%), pneumonia (22%), sepsis (excluding fungal; 19%), and hemorrhage (6%). The most common adverse reactions including hematological abnormalities (≥30%) of any grade were neutrophils decreased (98%), platelets decreased (94%), lymphocytes decreased (91%), hemoglobin decreased (61%), nausea (44%), diarrhea (43%), febrile neutropenia (42%), musculoskeletal pain (36%), pneumonia (33%), fatigue (31%), and vomiting (30%). Fatal adverse reactions occurred in 23% of patients who received VENCLEXTA in combination with azacitidine, with the most frequent (≥2%) being pneumonia (4%), sepsis (excluding fungal; 3%), and hemorrhage (2%).
- **In patients with AML receiving combination therapy with decitabine,** the most frequent serious adverse reactions (≥10%) were sepsis (excluding fungal; 46%), febrile neutropenia (38%), and pneumonia (31%). The most common adverse reactions including hematological abnormalities (≥30%) of any grade were neutrophils decreased (100%), lymphocytes decreased (100%), white blood cells decreased (100%), platelets decreased (92%), hemoglobin decreased (69%), febrile neutropenia (69%), fatigue (62%), constipation (62%), musculoskeletal pain (54%), dizziness (54%), nausea (54%), abdominal pain (46%), diarrhea (46%), pneumonia (46%), sepsis (excluding fungal; 46%), cough (38%), pyrexia (31%), hypotension (31%), oropharyngeal pain (31%), edema (31%), and vomiting (31%). One (8%) fatal adverse reaction of bacteremia occurred within 30 days of starting treatment.
- **In patients with AML receiving combination therapy with low-dose cytarabine,** the most frequent serious adverse reactions (≥10%) were pneumonia (17%), febrile neutropenia (16%), and sepsis (excluding fungal; 12%). The most common adverse reactions including hematological abnormalities (≥30%) of any grade were platelets decreased (97%), neutrophils decreased (95%), lymphocytes decreased (92%), hemoglobin decreased (63%), nausea (42%), and febrile neutropenia (32%). Fatal adverse reactions occurred in 23% of patients who received VENCLEXTA in combination with LDAC, with the most frequent (≥5%) being pneumonia (6%) and sepsis (excluding fungal; 7%).

Drug Interactions

- Concomitant use with a P-gp inhibitor or a strong or moderate CYP3A inhibitor increases VENCLEXTA exposure, which may increase VENCLEXTA toxicities, including the risk of TLS. Consider alternative medications or adjust VENCLEXTA dosage and monitor more frequently for adverse reactions. Resume the VENCLEXTA dosage that was used prior to concomitant use of a P-gp inhibitor or a strong or moderate CYP3A inhibitor 2 to 3 days after discontinuation of the inhibitor.
- Patients should avoid grapefruit products, Seville oranges, and starfruit during treatment as they contain inhibitors of CYP3A.
- Avoid concomitant use of strong or moderate CYP3A inducers.
- Monitor international normalized ratio (INR) more frequently in patients receiving warfarin.
- Avoid concomitant use of VENCLEXTA with a P-gp substrate. If concomitant use is unavoidable, separate dosing of the P-gp substrate at least 6 hours before VENCLEXTA.

Lactation

- Advise nursing women not to breastfeed during treatment with VENCLEXTA and for 1 week after the last dose.

Females and Males of Reproductive Potential

- Advise females of reproductive potential to use effective contraception during treatment with VENCLEXTA and for 30 days after the last dose.
- Based on findings in animals, VENCLEXTA may impair male fertility.

Hepatic Impairment

- Reduce the dose of VENCLEXTA for patients with severe hepatic impairment (Child-Pugh C); monitor these patients more frequently for adverse reactions. No dose adjustment is recommended for patients with mild (Child-Pugh A) or moderate (Child-Pugh B) hepatic impairment.

Please see additional Important Safety Information on pages 13-14.
Please see the full Prescribing Information.

VENCLEXTA PATIENT SUPPORT PROGRAMS

VENCLEXTA PATIENT SUPPORT PROGRAMS	
Genentech Access Solutions	VENCLEXTA Access Solutions is your patient's resource for helpful access and reimbursement support. (866) 422-2377 | **Genentech-Access.com/VENCLEXTA**
Genentech Patient Foundation	If patients don't have health insurance coverage or have financial concerns and meet eligibility criteria, they may be able to get free VENCLEXTA from the Genentech Patient Foundation. (888) 941-3331 | **Genentechpatientfoundation.com** To be eligible for free VENCLEXTA from the Genentech Patient Foundation, insured patients who have coverage for their medicine should try to pursue other forms of financial assistance, if available, and meet certain income requirements. Uninsured patients and insured patients without coverage for their medicine must meet a different set of income requirements. Genentech reserves the right to modify or discontinue the program at any time and to verify the accuracy of information submitted.
The Genentech Oncology Co-pay Assistance Program	The Genentech Oncology Co-pay Assistance Program provides financial assistance to eligible commercially insured patients to help with their out-of-pocket (OOP) costs.* (855) MY-COPAY / (855) 692-6729 | **CopayAssistanceNow.com** *Eligibility criteria apply. Not valid for patients using federal or state government programs to pay for their Genentech medicine. Patients must be taking the Genentech medicine for an FDA-approved indication. Please visit the Co-pay Program website for the full list of Terms and Conditions.
Referrals to independent co-pay assistance foundations	If eligible publicly or commercially insured patients have difficulty paying for their co-pay, co-insurance or other out-of-pocket (OOP) costs, VENCLEXTA Access Solutions can refer them to an independent co-pay assistance foundation supporting their diagnosis.† †Independent co-pay assistance foundations have their own rules for eligibility. Genentech and AbbVie have no involvement or influence in independent foundation decision-making or eligibility criteria and do not know if a foundation will be able to help your patient. We can only refer your patient to a foundation that supports their disease state. Genentech and AbbVie do not endorse or show preference for any particular foundation. The foundations to which we refer your patient may not be the only ones that might be able to help.
VENCLEXTA Nurse Support Line	You can speak with our Registered Nurses‡ about your treatment with VENCLEXTA—at no cost to you. Call our nurse support line: Monday–Friday, 7am–7pm CST. (844) 926-6727 ‡The nurses from the nurse support line are provided by AbbVie and do not work under the direction of a healthcare professional (HCP) or give medical advice. They are trained to direct patients to their HCP for treatment-related advice, including further referrals.

Please see Important Safety Information on pages 13–15.
Please see the full Prescribing Information.

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