Indication & Important Safety Information

Renvela® (sevelamer carbonate) is indicated for the control of serum phosphorus in adults and children 6 years of age and older with chronic kidney disease (CKD) on dialysis.

Important Safety Information for Renvela

- Renvela is contraindicated in patients with bowel obstruction and in patients with known hypersensitivity to sevelamer carbonate, sevelamer hydrochloride, or to any of the excipients.
- Caution should be exercised in patients with dysphagia, swallowing disorders, and severe gastrointestinal (GI) motility disorders, including severe constipation or major GI tract surgery.
- The most frequently occurring adverse reactions in a short-term study with sevelamer carbonate tablets were nausea and vomiting.
- In a short-term study of sevelamer carbonate powder dosed three times daily, adverse events were similar to those reported for sevelamer carbonate tablets.
- In long-term studies with sevelamer hydrochloride, which contains the same active moiety as sevelamer carbonate, the most common adverse events included vomiting, nausea, diarrhea, dyspepsia, abdominal pain, flatulence, and constipation.
- Other events reported include pruritus, rash, fecal impaction and, less commonly, ileus, bowel obstruction, and bowel perforation.
- Uncommon cases of difficulty swallowing the Renvela tablet have been reported. Caution should be exercised in these patients and consideration given to using sevelamer suspension in patients with a history of difficulty swallowing.
- Drug-drug interactions may occur with some medications and should be taken into consideration when instructing patients how to take Renvela.
- Serum bicarbonate and chloride levels should be monitored.
- Follow patients for reduced vitamins D, E, and K (coagulation parameters) and folic acid levels.
- Patients should be informed to take Renvela with meals and to adhere to their prescribed diets.

Hectorol (doxercalciferol) Injection is indicated for the treatment of secondary hyperparathyroidism in patients with chronic kidney disease on dialysis.

Important Safety Information for Hectorol Injection

- Hectorol is contraindicated in patients with a tendency towards hypercalcemia, or evidence of vitamin D toxicity and in patients with previous hypersensitivity to doxercalciferol or any of its ingredients.
- Overdosage of any form of vitamin D is dangerous and may lead to progressive hypercalcemia, which if severe, may require emergency attention.
- Acute hypercalcemia may exacerbate tendencies for cardiac arrhythmias and seizures and may potentiate the action of digitalis drugs.
- Chronic hypercalcemia can lead to generalized vascular and other soft tissue calcification.
- Pharmacologic doses of vitamin D and its derivatives should be withheld during Hectorol treatment to avoid possible additive effects and hypercalcemia.
- The patient should be informed about adherence to instructions about diet, calcium supplementation, and avoidance of the use of nonprescription drugs without prior physician approval. Patients should also be carefully informed about the symptoms of hypercalcemia such as weakness, headache, drowsiness, nausea, vomiting, dry mouth, constipation, muscle pain, bone pain, metallic taste and loss of appetite.
- Uncontrolled serum phosphorus in patients undergoing dialysis may lessen the effectiveness of Hectorol.
- Magnesium-containing antacids and Hectorol should not be administered concomitantly.

Continued on next page

Please click here to see full Prescribing Information for Renvela and Hectorol.

Important Safety Information for Hectorol (doxercalciferol) Injection, continued

- Serious hypersensitivity reactions, including fatal outcome, have been reported post marketing in patients on hemodialysis following administration of Hectorol Injection. Hypersensitivity reactions include anaphylaxis with symptoms of angioedema (involving face, lips, tongue and airways), hypotension, unresponsiveness, chest discomfort, shortness of breath, and cardiopulmonary arrest. These reactions may occur separately or together
- Monitor patients receiving Hectorol Injection upon initiation of treatment for hypersensitivity reactions. Should a hypersensitivity reaction occur, discontinue Hectorol, monitor and treat if indicated
- Enzyme inducers may affect the 25-hydroxylation of Hectorol and may necessitate dosage adjustments. Cytochrome P450 inhibitors may inhibit the 25-hydroxylation of Hectorol. Formation of the active Hectorol moiety may be hindered.
- Adverse effects of Hectorol injection treatment are: hypercalcemia, hyperphosphatemia, and oversuppression of iPTH. These should be managed by regular patient monitoring and appropriate dosage adjustments.
- Serum levels of iPTH, calcium and phosphorus should be determined prior to initiation of Hectorol treatment. During the early phase of treatment they should be determined weekly.
- Adverse events reported by ≥5% of the Hectorol-treated dialysis patients included: edema, headache, malaise, nausea/vomiting, dizziness, dyspnea, pruritus and bradycardia.
- This drug should be used during pregnancy only if clearly needed.
- Nursing mothers should discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.
- This drug should be used with caution in patients with impaired hepatic function.

Please click here to see full Prescribing Information for Renvela and Hectorol.

2017 Renassist® Insurance Verification Form & Patient Assistance Application
Instructional Page

INSURANCE VERIFICATION

Please submit page 1 only. The patient may sign and date the consent at the bottom of page 1.

Insurance verifications are available for patients whose prescribers have identified Renvela® (sevelamer carbonate) or Hectorol® (doxercalciferol) to be clinically appropriate. Renassist can provide insurance plan details that may allow patients to better access the prescribed product and/or provide guidance on potential assistance programs.

Renassist can help remove access barriers if the patient's insurance plan requires prior authorization facilitation, tier exception, or formulary exception.

APPLYING FOR ASSISTANCE WITH RENVELA AND/OR HECTOROL

Please submit pages 1 and 2. The patient may sign and date the consent at the bottom of page 2.

Thank you for your interest in the Renassist Patient Assistance Program. If you are having trouble affording your Renvela or Hectorol, this program may be appropriate for you. The type of assistance available varies based on the medicine that has been prescribed for you, your household income, and your insurance status.

To receive prescription medicine assistance from Renassist, you and your doctor must complete and submit this application form in its **entirety**, and meet program eligibility requirements. We have included a checklist to guide you through completing and submitting your application.

If you have any questions, please call Renassist at 1-800-847-0069. Renassist Case Managers are available to answer your calls Monday through Friday, from 9 AM to 4:30 PM Eastern Time, except for Holidays.

APPLICATION CHECKLIST: Use this to help make sure you complete and submit your application properly

- ☐ Provider information (name, address, phone, fax, and NPI/DEA)
- ☐ Primary contact information (full name, title, and email)
  Contact information will be used for follow-up communication
- ☐ Patient information
- ☐ Front and back copies of all insurance cards
- ☐ Financial information (monthly values only)
- ☐ Valid and legible prescription (filled for a 3 month supply)
- ☐ Shipping details - *Please note: **prescription delivery requires a signature***
  Preferred method of delivery is to provider's office, unless otherwise prohibited.
- ☐ Patient signature and date on page 2
- ☐ Power of Attorney Documentation (if applicable)

Submission of a complete application form does not guarantee enrollment. Incomplete applications will be returned and will result in a processing delay. Each application will be considered on a case-by-case basis.

Federal Poverty Level Guidelines (FPLs)*

	48 Contiguous States and DC		Alaska		Hawaii	
Persons in family	150% Monthly	300% Monthly	150% Monthly	300% Monthly	150% Monthly	300% Monthly
1	$1,507.50	$3,015.00	$1,882.50	$3,765.00	$1,732.50	$3,465.00
2	$2,030.00	$4,060.00	$2,536.25	$5,072.50	$2,333.75	$4,667.50
3	$2,552.50	$5,105.00	$3,190.00	$6,380.00	$2,935.00	$5,870.00

For FPL information for households larger than 3, please contact Renassist at 1-800-847-0069.

If household gross income is below 150% of the FPL, apply for LIS (Extra Help) through the Social Security Administration at 1-800-772-1213 or www.socialsecurity.gov/prescriptionhelp.

*The FPL amounts could change based on Federal regulations.

Please click here to see full Prescribing Information for Renvela and Hectorol.

♦ Phone: 1.800.847.0069 (M – F , 9am – 4 :30pm EST) ♦ Fax: 1.877.363.6732 ♦ Email: renassist@sanofi.com ♦ Web: www.renassist.com ♦

2017 Social Security Administration Low Income Subsidy (LIS) Overview

AM I ELIGIBLE FOR LIS?

2017 Low Income Subsidy	
What is LIS?	LIS, also known as "Extra Help," assists Medicare beneficiaries with paying all or a portion of their Medicare Prescription Drug Plan's premium, annual deductible, and/or co-payments. Beneficiaries may be eligible for a full subsidy or partial subsidy based on their income and assets. Beneficiaries must be enrolled in Medicare to be eligible to receive the extra help. Source: https://secure.ssa.gov/POMS.NSF/lnx/0603001005
Who is eligible for LIS?	Eligibility for LIS is determined by the Social Security Administration or the state Medicaid office (for beneficiaries with both Medicare and Medicaid). To qualify for LIS, applicants must reside in one of the 50 states or the District of Columbia and meet the following eligibility criteria: Income levels are within the Federal Poverty Level ranges described below: • **Full Subsidy**: Income at or below 135% Federal Poverty Level (up to $1,356.75 monthly for an individual or up to $1,827.00 monthly for a married couple) • **Partial Subsidy**: Income above 135% Federal Poverty Level but at or below 150% FPL (up to $1,507.50 monthly for an individual or up to $2,030.00 monthly for a married couple) Resources (combined savings, investments, and real estate other than primary residence) are within the ranges described below: • **Full Subsidy**: Resources up to $8,890 per individual or $14,090 per married couple • **Partial Subsidy**: Resources up to $13,820 per individual or $27,600 per married couple Source: https://secure.ssa.gov/POMS.NSF/lnx/0603001005

Federal Poverty Level Guidelines (FPLs)*

	48 Contiguous States and DC		Alaska		Hawaii	
Persons in family	135% Monthly	150% Monthly	135% Monthly	150% Monthly	135% Monthly	150% Monthly
1	$1,356.75	$1,507.50	$1,694.25	$1,882.50	$1,559.25	$1,732.50
2	$1,827.00	$2,030.00	$2,282.63	$2,536.25	$2,100.38	$2,333.75
3	$2,297.25	$2,552.50	$2,871.00	$3,190.00	$2,641.50	$2,935.00

For FPL information for households larger than 3, please contact Renassist at 1-800-847-0069.

*The FPL amounts could change based on Federal regulations.

Applying for Extra Help

How do you apply for LIS?	Complete and submit an application either over the telephone by calling the Social Security Administration at 1-800-772-1213 or online at www.ssa.gov/prescriptionhelp/.

2017 Renassist® Insurance Verification Form & Patient Assistance Application

Please fax completed form to Renassist, Sanofi US at 877-363-6732 or email to renassist@sanofi.com

Renvela® (sevelamer carbonate) 800mg Tablets ☐	Renvela® (sevelamer carbonate) 2.4g Powder Packets ☐	Hectorol® (doxercalciferol) Injection (2mcg/mL vial) ☐	Hectorol® (doxercalciferol) Injection (4mcg/mL vial) ☐

Insurance Verification ☐	**Patient Assistance** ☐
Complete page 1 only. Patients with Rx coverage (i.e. commercial insurance or Medicare Part D) choose this option.	Complete both pages. Patients with Medicare Part D or no Rx coverage choose this option.

PROVIDER INFORMATION

Dialysis Unit Name:	Prescriber Name/Title:
Dialysis Unit Tax ID #:	Prescriber NPI #:
Unit Address:	MD Office Address:
City, State, Zip:	City, State, Zip:
Unit Phone:	MD Office Phone:
Unit Fax:	MD Office Fax:
Contact Name/Title:	
Contact Email:	

PATIENT INFORMATION

First Name:	Last Name:	Suffix:
SSN:	Date of Birth: _____/_____/_____	Gender: M F
Apt. #:	Street Address:	
City, State, Zip:	Email:	
Primary Phone:	Secondary Phone:	

US Citizen: Yes No *If No, please attach a copy of the patient's Green Card or Permanent Resident Card.*

NEW START: First Date of Dialysis: _____/_____/_____ Date Applied to Medicare: _____/_____/_____

INSURANCE DETAILS

Are you enrolled in Medicare?	Yes ☐	Medicare Policy ID#: _____ Effective Date: _____/_____/_____ *ID # and Effective Date are on the red, white, and blue Medicare card*
	No ☐	☐ Not enough working quarters ☐ Green Card or Permanent Resident Card attached
Insurance Card Copies are Required *Please check all that apply*	☐ Medicare Part D ☐ Medicare Advantage Plan ☐ Private Insurance ☐ VA Benefits ☐ Medicaid ☐ Emergency Medicaid ☐ Medicare Supplement ☐ No Insurance	*If copies of cards aren't available, please contact Renassist at 1-800-847-0069*

PATIENT RELEASE OF INFORMATION

The Sanofi US ("Sanofi") Renassist program must have the patient's authorization to conduct a benefit verification and insurance research. By providing authorization, the patient ("you") permits Sanofi and/or its affiliates to contact the insurer(s), including Medicare, about Chronic Kidney Disease (CKD) related therapies and allows the insurer(s) to disclose the relevant information about you to Sanofi. Sanofi may need to provide the insurer(s) with your name, date of birth, Social Security number, diagnosis, insurance information, or other relevant information about you. Sanofi may also contact you directly for missing or additional information required to process this verification request. If you understand the foregoing and authorize the sharing of the above information between your dialysis unit, prescribing physician, insurer(s), Medicare, and Sanofi's Renassist program, please sign below. By signing below, you also hereby authorize Sanofi to contact you directly in the future about available assistance programs, CKD treatment and therapies, and/or reimbursement and access related information. Sanofi respects your interest in keeping your personal information private. We will not sell or rent your information to any outside third parties or mailing lists. The information you provide will only be used by Sanofi or its authorized third parties, such as EnvoyHealth Management, LLC and the American Kidney Fund, to provide you with the information and materials that are made available as part of the Renassist program. You understand and agree that your consent to be contacted is a condition of participation in the Renassist program. However, your consent is not a condition of purchase of any goods or services. You may unsubscribe from the Renassist program at any time by visiting https://unsubscribe.sanofi-aventis.us or by calling 1-800-847-0069.

X Patient Signature: _____ **Date:** _____/_____/ **2017**

Please click here to see full Prescribing Information for Renvela and Hectorol.

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2017 Renassist® Patient Assistance Application

FINANCIAL INFORMATION

Household Size If you were to report household size on a legal tax document, how many people (including yourself) would you indicate? (i.e. Self + Spouse + 1 Dependent = 3)	Total number of people in your household: 1 2 3 4 5 6 *Please do not include roommates*
MONTHLY Household GROSS Income: BEFORE Deductions/Taxes Combined income for you, your spouse, and dependents (i.e. wages/employment, Social Security, retirement, pension, Veteran's benefits, aid for dependent children)	$ NUMERICAL VALUE REQUIRED
MEDICARE BENEFICIARIES	***If your gross household income is below 150% of the Federal Poverty Level (FPL), your first line of assistance is to apply for LIS (Low Income Subsidy) aka Extra Help through the Social Security Administration. If your gross income is below 150% of the FPL, please attach the LIS denial letter in order for the application to be processed.***
MONTHLY Household NET Income: AFTER Deductions/Taxes Combined income for you, your spouse and dependents. Excluding Medicare premiums.	$ NUMERICAL VALUE REQUIRED
Current Household Assets Combined assets for you, your spouse, and dependents (i.e. savings account, stocks, bonds; *excluding* primary residence, IRA, 401k)	$ NUMERICAL VALUE REQUIRED
MONTHLY Household Expenses Combined expenses for you, your spouse, and dependents (i.e. rent/mortgage, transportation, utilities, medications, food, insurance, car, loan and credit card payment)	$ NUMERICAL VALUE REQUIRED

PATIENT ATTESTATION AND RELEASE OF INFORMATION

The Sanofi US ("Sanofi") Renassist program must have the patient's authorization to determine eligibility for patient assistance and to conduct insurance research. By providing authorization, the patient ("you") permits Sanofi and/or its affiliates and its authorized third parties such as the American Kidney Fund, ("AKF") and EnvoyHealth Management, LLC ("EnvoyHealth") to; (1) share patient assistance eligibility information with EnvoyHealth (for Part D patients), with AKF (for other patients), your dialysis unit, and prescribing physician and (2) to contact your insurer(s), including Medicare, about Chronic Kidney Disease (CKD) related therapies and allows the insurer(s) to disclose the relevant information to Sanofi. Sanofi may need to provide EnvoyHealth, AKF, and the insurer(s), including Medicare, with your name, date of birth, Social Security Number, diagnosis, insurance information, or other relevant information about you. Sanofi and AKF may also contact you directly for missing or additional information required to process this patient assistance request. By signing below, I attest that the financial information I have provided is complete and accurate and I agree that AKF and/or Sanofi may verify this information. By signing below I also authorize Sanofi to contact me directly in the future about available assistance programs, CKD treatment and therapies, and/or reimbursement and access related information. Sanofi respects your interest in keeping your personal information private. We will not sell or rent your information to any outside third parties or mailing lists. The information you provide will only be used by Sanofi or its authorized third parties, such as, its affiliates and business service companies performing services on behalf of Sanofi, to provide you with the information and materials that are made available as part of the Renassist Program. You understand and agree that your consent to be contacted is a condition of participation in the Renassist program. However, your consent is not a condition of purchase of any goods or services. You may unsubscribe from the Renassist program at any time by visiting https://unsubscribe.sanofi-aventis.us or by calling 1-800-847-0069.

PRINT PATIENT NAME: _____ **DOB:** _____/_____/ _____

X PATIENT SIGNATURE: _____ **DATE:** _____/_____/ **2017**

℞ PRESCRIPTION: TO BE COMPLETED BY A LICENSED PRESCRIBER ONLY

Rx Shipping Confirmation Ship drug to (address and contact listed on Page 1): **Unit** ☐ **MD Office** ☐ **Patient** ☐

Delivery requires a signature and cannot be shipped to a PO Box

Select Product(s)	Directions (please write Rx clearly for a ***3-month supply***)
Renvela (sevelamer carbonate) 800mg Tablets ☐	**Total per day** ____ Tablets ____ Packets
Renvela (sevelamer carbonate) 2.4g Powder Packets ☐	
Hectorol (doxercalciferol) Injection 2mcg/mL Vial ☐	
Hectorol (doxercalciferol) Injection 4mcg/2mL Vial ☐	

Product(s) to be filled for a 3 month supply with refills authorized for up to 1 year from original date of this prescription. Part D Assistance product will be supplied until 12/31/2017. Dispensing pharmacy may reduce quantities dispensed in accordance with program guidelines and program eligibility requirements. Product(s) will be shipped to the attention of the Primary Contact indicated in the Rx Shipping Confirmation box above, unless otherwise prohibited. I understand that I am under no obligation to prescribe any Sanofi product and that I have not received nor will I receive any benefit from Sanofi or their agents or representatives for prescribing a Sanofi product.

Print Prescriber Name: _____ **DEA#/NPI#:** _____

X Prescriber Signature: _____ **Date:** _____/_____/ _____

Please click here to see full Prescribing Information for Renvela and Hectorol.

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