Instructions: How to Complete Statement of Medical Necessity (SMN)
for LUCENTIS® (ranibizumab injection)

Phone: (866) 724-9394 Fax: (866) 724-9412 www.LUCENTIS.com

LUCENTIS® RANIBIZUMAB INJECTION
Access Solutions™ Treatment made possible.™

Please write legibly and complete all sections to prevent delay.

Services Requested

- Please indicate the services that are being requested to allow LUCENTIS® Access Solutions™ to proceed accordingly.

Attach to Completed SMN

- Please attach a signed and dated PATIENT AUTHORIZATION AND NOTICE OF RELEASE OF INFORMATION (PAN) form. This form is needed to fully investigate coverage.

Insurance Information

- Fill out this section with the patient's insurance information, **OR** provide a front and back copy of the patient's insurance card (enlarged and legible), and fax this information with the SMN and PAN.
- Including both primary and secondary insurance will ensure that all potential coverage can be investigated.

Diagnosis and Medical Information

Additional medical information

- Check the box if you are faxing back additional information such as test results.

Diagnosis

- Check the appropriate diagnosis code.
- If "other" is checked, ICD-9 code is required.

Eye(s) affected

- Check the appropriate box to indicate which eye is affected, including any existing disease.

Eye(s) being treated

- Check the appropriate box to indicate which eye is being treated currently.

Visual acuity in Rt/Lt eye

- Please enter visual acuity information.

Additional information

- Please enter any information here that you feel is pertinent to the patient's treatment (optional).

Has patient started treatment/Anticipated treatment date

- Please check either "yes" or "no." If the patient has not started treatment, enter the anticipated date of the first treatment.

Prescription

- Please ensure that you complete all areas of the prescription portion correctly and completely.
- A prescription cannot be processed with a stamped signature. The prescriber must sign and date the form to make the prescription valid.
- LUCENTIS can be dosed monthly using 0.5 mg (0.05 mL), or 0.5 mg (0.05 mL) monthly for three months, then quarterly.
- LUCENTIS should be refrigerated at 2-8°C (36-46°F). Please indicate where to send shipments (if different from the prescriber address) to ensure that the drug will be stored appropriately.

Reminder

This form cannot be processed without a prescriber's signature and date as well as a signed and dated PAN form.

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Please complete with a ballpoint pen.

Services Requested (Check All That Apply)

☐ Benefits Investigation/Prior Authorization ☐ Appeals Assistance ☐ Genentech® Access to Care Foundation ☐ Specialty Pharmacy Referral

Patient Information

Last Name: First Name:

Street: City: State: ZIP:

Home Phone: ( ) Cell or Work Phone: ( )

Date of Birth (MM/DD/YR): ☐ Male ☐ Female

Alternate Contact Name: **Relationship:** Phone: ( )

Patient E-mail Address:

Is it OK for LUCENTIS Access Solutions to contact patient? ☐ **Yes** ☐ **No**

Insurance Information

☐ Insurance card attached (optional: see reverse for details)

☐ HMO/EPO ☐ PPO ☐ POS ☐ Indemnity ☐ Medicare ☐ No Insurance	☐ HMO/EPO ☐ PPO ☐ POS ☐ Indemnity ☐ Medicare ☐ No Insurance
Primary Insurance Name:	Secondary Insurance Name:
Phone: ( )	Phone: ( )
Subscriber:	Subscriber:
Subscriber ID #: Grp #:	Subscriber ID #: Grp #:
Employer: ☐ Retired	Employer: ☐ Retired

Diagnosis and Other Pertinent Medical Information

☐ Additional pertinent medical information has been attached (optional)

DIAGNOSIS: ☐ WET FORM AGE-RELATED MACULAR DEGENERATION (362.52) ☐ OTHER; PLEASE SPECIFY ICD-9

Eye(s) Affected: (check all that apply) ☐ Rt ☐ Lt

Eye(s) Being Treated: (check all that apply) ☐ Rt ☐ Lt

Visual Acuity in Rt Eye: /

Visual Acuity in Lt Eye: /

Additional Information (if any):

Has Patient Started Treatment? ☐ Yes ☐ No Anticipated Date of Treatment:

Prescription and Prescriber Information

LUCENTIS® (ranibizumab injection) ☐ NKDA ☐ Drug Allergies: _____

DISPENSE: _____ vial(s) (each vial contains 0.05 mL of a 10-mg/mL solution)

Refill: ____ times

SIG: ☐ Inject 0.5 mg (0.05 mL) intravitreally monthly

SIG: ☐ Inject 0.5 mg (0.05 mL) intravitreally monthly x3 months then quarterly

SIG: ☐ _____

Ship to Address (if different than office shown below):

Prescriber's Full Name: DEA #: Tax ID #:

State License #: Prescriber NPI*: Group Billing NPI:

Street: City: State: ZIP:

Practice Reimbursement Contact: Phone: ( ) Fax: ( )

UNAPPROVED USE WARNING: Please read the FDA-approved label for LUCENTIS before prescribing. If the indication for which you are prescribing LUCENTIS is not listed in the label, you are prescribing LUCENTIS for an "unapproved" use. The fact that the use for which you are prescribing LUCENTIS is not listed in the FDA-approved label indicates that the FDA has not approved the efficacy, dosage amount or safety of LUCENTIS when used for such a use. Nevertheless, Genentech® Access to Care Foundation will consider providing LUCENTIS for your patient with this admonition, based upon your medical order, within program requirements.

- By signing below, I certify that (a) the above therapy is medically necessary, (b) I have received the necessary authorization to release the above-referenced information and other protected health information (as defined in the Health Insurance Portability and Accountability Act of 1996 [HIPAA]) to Genentech USA, Inc., LUCENTIS® Access Solutions™ and contracted dispensing pharmacy or other contractors for the purpose of seeking reimbursement, assisting in initiating or continuing therapy and/or the evaluation of the patient's eligibility for the Genentech Access to Care Foundation program related to Genentech products, as a break in treatment would negatively impact the patient's therapeutic outcome, (c) I will not sell or bill for any free product received in my office for patients from the Genentech Access to Care Foundation program, and (d) I appoint LUCENTIS Access Solutions solely to convey on my behalf to the pharmacy chosen by the above-named patient the prescription described herein.
- I agree to comply with the program guidelines as established by Genentech USA, Inc. and understand that Genentech Access to Care Foundation, at its sole and absolute discretion, reserves the right to modify or discontinue the program at any time and to verify the accuracy of the information submitted.

Prescriber Signature: Date:

Original signature required for a valid prescription.

*National Provider Identifier

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PATIENT AUTHORIZATION AND NOTICE
OF RELEASE OF INFORMATION

Phone: (866) 724-9394 Fax: (866) 724-9412 www.LUCENTISAccessSolutions.com

Dear Patient:

LUCENTIS® Access Solutions™ is a program sponsored by Genentech USA, Inc. that provides support services such as benefits investigations, prior authorizations and appeals assistance at no charge to patients and assists patients in obtaining reimbursement for LUCENTIS (ranibizumab injection). If a patient does not have insurance or is deemed uninsured due to denial by private and public payers, and the patient meets certain financial criteria, the Genentech® Access to Care Foundation may provide LUCENTIS free of charge. Additional information on these programs can be found at www.LUCENTISAccessSolutions.com.

In order for LUCENTIS Access Solutions and Genentech Access to Care Foundation to provide the described services, we will need to review, use and disclose your protected health information (PHI). By law, only with your prior written authorization may your health care provider, health plan or health insurer disclose your PHI to LUCENTIS Access Solutions and Genentech Access to Care Foundation. As soon as we obtain your prior written authorization, we will work to provide you with the services.

You are not required to agree to this Authorization. However, failure to provide this Authorization may prevent you from becoming eligible for the LUCENTIS Access Solutions coverage and reimbursement assistance or Genentech Access to Care Foundation patient assistance programs, which may result in your need to pay for certain products with your own funds. You will receive a copy of the Authorization you sign. Please review this Authorization carefully. If you have any questions regarding this Authorization, please contact your health care provider's office. Contact information is included below.

I. Information to Be Disclosed or Used

This Authorization permits my health care providers, health plans and health insurers who provide services to me to use and disclose to LUCENTIS Access Solutions or Genentech Access to Care Foundation, its authorized agents and assignees, all medical records and financial information with respect to my treatment that may have bearing on the benefits payable for services or products provided through my health care provider, health plan or insurer under any plan providing benefits or services, including, without limitation, the dollar balance of benefits remaining under any applicable lifetime maximum benefits provisions, or that may have bearing on my medical condition or compliance with therapy. All of this information may be considered PHI, and may, if relevant, include information about HIV/AIDS and/or other communicable diseases, mental health information, and/or information concerning genetic test results.

II. Persons Authorized to Disclose Information

The PHI identified in Paragraph I may be disclosed by my health care provider, health plan, health insurer or others who may hold my PHI.

III. Persons to Whom Disclosure May Be Made

The PHI identified in Paragraph I may be disclosed to and/or used by LUCENTIS Access Solutions or Genentech Access to Care Foundation, their sponsor Genentech USA, Inc., a biopharmaceutical manufacturer located at 1 DNA Way, Mail Stop #210, South San Francisco, CA 94080, and its related entities, their agents or assignees, and certain Genentech business partners, such as Novartis Pharmaceuticals Corporation, as well as other companies involved in the administration of certain Genentech products.

IV. Description of Each Purpose

My PHI may be used for the purposes of reimbursement and/or participation in a coverage and reimbursement assistance or patient assistance program administered by LUCENTIS Access Solutions and Genentech Access to Care Foundation, respectively. My PHI may also be used for purposes of tracking the general use of a Genentech product, assessing and improving Genentech's coverage and reimbursement and patient assistance services, and proper management and administration of Genentech's business.

V. Expiration Date or Event

California residents only: This Authorization will be effective, unless revoked by me in writing, until December 31, 2015.

All other residents: This Authorization will be effective, unless revoked by me in writing, for up to one year from the date of this Authorization.

VI. Notices

I understand that once my health information is disclosed pursuant to this Authorization, there is no guarantee under federal law that the recipient will not redisclose my health information to a third party. Any such third party may not be required to abide by this Authorization or applicable federal law governing the use and disclosure of my health information.

I understand that I may refuse to sign or may revoke (at any time) this Authorization for any reason and that such refusal or revocation will not affect the commencement, continuation or quality of my health care provider's treatment of me. If I refuse to sign or revoke this Authorization, however, I may be responsible for costs that may have otherwise been covered by LUCENTIS Access Solutions or Genentech Access to Care Foundation.

I understand that this Authorization will remain in effect until it expires as described above or I provide a written notice of revocation via mail to LUCENTIS Access Solutions, 1 DNA Way, Mail Stop #210, South San Francisco, CA 94080, or via fax to (866) 724-9412. The revocation will be effective immediately upon my health care provider's receipt of my written notice, except that the revocation will not have any effect on any action taken by my health care provider or others referenced in this Authorization, including without limitation, LUCENTIS Access Solutions or Genentech Access to Care Foundation, in reliance on this Authorization before my health care provider received my written notice of revocation.

VII. Distribution Acknowledgment

I also hereby state (or my parent/guardian hereby states) that I will utilize LUCENTIS for the reason that my physician has prescribed it to me. I will not sell or distribute LUCENTIS, as I acknowledge it is unlawful to do so. I will be responsible to ensure that LUCENTIS will be delivered to a secure address for purposes of receipt of shipment, and I understand it is my duty to control LUCENTIS while it remains in my possession.

VIII. Signature

SIGNATURE REQUIRED

I have read and I understand the terms of this Authorization, and I have had an opportunity to ask questions about the use and disclosure of my health information. By my signature below, I hereby, knowingly and voluntarily, authorize the use and/or disclosure of my health information in the manner described above.

Print Patient's Name (required) | Signature of Patient or Guardian* (required) | Description of Authority (required)

Patient's/Guardian's Address (required)

*If the patient is an unemancipated minor or otherwise incapacitated (physically or mentally).

Date (required)

IX. Financial Information

- Only uninsured patients (and patients whose insurance has denied treatment) who wish to apply to the Genentech Access to Care Foundation for assistance need to fill out this section.
- There is no need to complete this section if the patient has insurance coverage for LUCENTIS.

COMPLETE IF NECESSARY

Household Adjusted Gross Income:
☐ $0-25K/yr ☐ $25,001-50K/yr
☐ $50,001-75K/yr ☐ $75,001-100K/yr

I understand that in order to qualify, my adjusted gross income may not exceed $100K/yr. I certify that the above statement of my previous year's income is true and that I have no medical insurance coverage for LUCENTIS, including Medicare, Medicaid or other public programs, and that I have insufficient financial resources to pay for the prescribed therapy. I also agree to furnish my IRS 1040 (or if none, then my Social Security Benefit Statement or W-2) within 45 days of the submission of this form. I understand that failure to provide this documentation may result in an interruption in therapy.

Signature of Patient (complete if applicable) | Date Signed (complete if applicable)

Eye on AMD™ Patient Support Program

OPTIONAL

I authorize Genentech to enroll me in *Eye on AMD*, a patient support program. I understand that my name, address, e-mail address, phone number and the name of my pharmacy, once provided by me, will be sent by LUCENTIS Access Solutions to *Eye on AMD* to complete my enrollment. I agree that Genentech and its agents may contact me in the future by mail, e-mail and/or telephone concerning the *Eye on AMD* program. I understand that all my personally identifiable information will be kept strictly confidential and will not be distributed outside of Genentech or its agents, as the Genentech USA, Inc. privacy policy provides (available at www.LUCENTIS.com). I also understand that I do not have to sign this Authorization in order to receive LUCENTIS or participate in the LUCENTIS Access Solutions/Genentech Access to Care Foundation programs and that I may cancel this Authorization at any time by giving written notice to Genentech through its agent at PO Box 29342, Mission, KS 66201-9627.

Signature of Patient (optional) | Patient's E-mail Address (optional) | Date (optional)

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LUCENTIS® (ranibizumab injection)

FAX COVER SHEET

Attn: Genentech® Access to Care Foundation	**Date:**
To:	**Fax #:** (866) 724-9412
From:	**Phone:**
	# Pages:

LUCENTIS® (ranibizumab injection)

Patient's Name: Date of Birth:

Comments: