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**ROP Safety Net Toolkit**

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**Reviewed by**

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**OMIC policyholders who provide care must comply with the ROP Safety Net.**

OMIC’s ROP Safety Net is based on our claims experience. It is designed to address the causes of ROP lawsuits in order to protect the infant and the ophthalmologist. The ROP Safety Net Toolkit contains sample protocols, which may need to be customized, and refers to ROP clinical care guidelines. These protocols and guidelines are recommendations and do not constitute the standard of care. Ophthalmologists should use their professional judgment in determining the applicability of a given recommendation to their particular patients and practice situation.

The Toolkit does not provide legal advice. Consult an attorney if legal advice is desired or needed. Information contained here is not intended to be a modification of the terms and conditions of the OMIC professional and limited office premises liability insurance policy. Please refer to the OMIC policy for these terms and conditions.

**Version 2/14/19**

# **Procedure 3a. Treat ROP at hospital**

**Treat ROP at hospital principles**

1. The hospital has a treating ophthalmologist available to provide ROP treatment within 72 hours of notice that it is needed.
2. The hospital either allows infants discharged from the NICU to be readmitted for ROP treatment or has a transfer agreement in place with a hospital that does allow discharged infants to be admitted for ROP treatment within 72 hours of notice that it is needed.
3. The hospital is able to provide anti-VEGF drugs at the appropriate compounded dose and supplies for intravitreal injections.
4. The hospital has an ROP coordinator (H-ROPC) who is familiar with and understands the ROP Screening Policy Statement (PS)[[1]](#footnote-1) and the Tables in the ROP toolkit that are based upon it, and is able to use the Tables to review and clarify the appropriateness of follow-up and treatment intervals, and coordinate discharge or transfer.
5. The ophthalmologist:
	1. Has sufficient knowledge and experience to identify accurately the location and sequential retinal changes of ROP after pupillary dilation using binocular indirect ophthalmoscopy (BIO) with a lid speculum and scleral depression if needed, per the PS.
	2. Uses the International Classification of Retinopathy of Prematurity (ICROP) Revisited[[2]](#footnote-2)to classify, diagram, and record the retinal findings.
	3. Knows and understands treatment criteria [[Table 4. When to treat](#_Table_4._)].

**Treatment process**

**Use the hyperlinks to see tables and forms. To go back to where you were in the document on a PC, press Alt+left arrow.**

1. The screening ophthalmologist determines that treatment might be needed [[Table 4. When to treat](#_Table_4._)], documents the findings using ICROP, and notifies the neonatologist and ROPCs.
2. The screening ophthalmologist conducts and documents a transfer-of-care discussion with the treating ophthalmologist if another ophthalmologist will provide the treatment.
3. The treating ophthalmologist obtains informed consent for the treatment [[Consent for laser](#_Consent_for_laser), [Spanish consent for laser](#_Consentimiento_para_cirugía), [Consent for injection](#_Consent_for_injection_2), or [Spanish consent for injection](#_ICROP._Synopsis_of)].
4. The H-ROPC schedules the procedure, and confirms that treatment will be provided within 72 hours.
5. The treating ophthalmologist performs and documents the procedure, and informs the parents of the results and when the follow-up exam will take place.
6. The treating ophthalmologist informs the ROPCs of the date and type of treatment and when the next exam is needed, giving both the interval and approximate date of the exam [[Table 3. Follow-up exams](#_Table_3._)]. Current guidelines suggest that the ophthalmologist should examine the eye 3 to 7 days after treatment.
7. The treating ophthalmologist reexamines the eye to determine if more treatment is needed.
	1. The H-ROPC contacts the O-ROPC of the screening ophthalmologist if the treating ophthalmologist does not perform the follow-up exams.
	2. The treating ophthalmologist contacts the screening ophthalmologist and conducts and documents the transfer-of-care discussion.
8. The ophthalmologist notifies the ROPCs when treatment is complete, and instructs both to update the Hospital ROP Tracking List.
9. The ophthalmologist continues to examine, treat, and track the infant until **one** of these criteria to end screening/treatment has been met and documented:
	1. ***Per the Policy Statement, one exam is sufficient only if it unequivocally shows the retina to be fully vascularized in both eyes.***
	2. A treating ophthalmologist has confirmed that all treatment and follow-up examinations are complete
	3. Both eyes have met the conclusion-of-acute-screening criteria based upon a BIO exam [[Table 5. When to stop ROP](#_Table_5._)].
	4. The current ophthalmologist conducts and documents a transfer-of-care discussion with the ophthalmologist who will take over care.
10. The ophthalmologist informs the neonatologist and ROPCs of the need for an outpatient screening exam for eye conditions associated with prematurity if ROP screening is complete.

# [**Table 1. Which infants need an ROP screening examination**](#Table_1)**[[3]](#footnote-3)**

Infants meeting any of the following criteria need an exam:

* Birth weight of ≤ 1500 g (3 lbs., 4 oz.)
* Gestational age of 30 weeks or less (as defined by the attending neonatologist)
* Selected infants with a birth weight between 1500 and 2000 g (from 3 lbs., 4 oz. to 4lbs, 6 oz.) or gestational age of more than 30 weeks who are believed by their attending pediatrician or neonatologist to be at risk for ROP (such as infants with hypotension requiring inotropic support, infants who received oxygen supplementation for more than a few days, or infants who received oxygen without saturation monitoring).

**REFERENCE: ROP Screening Policy Statement # 1**. Based on Recchia, Franco and Capone, Antonio, Contemporary Understanding and Management of Retinopathy of Prematurity, *Retina* 2004; 24:283-92.

# [**Table 2. When to start ROP screening**](#Table_2)

The onset of serious ROP correlates better with postmenstrual age (gestational age at birth plus chronological age) than with postnatal age. This protocol bases the initial eye examination on postmenstrual age and chronological age. The initial eye examination should be conducted:

* By 31 weeks postmenstrual age if gestational age < 27 weeks
* At 4 weeks chronological age if gestational age ≥ 27 weeks

 **Age in weeks at initial exam**

|  |  |  |
| --- | --- | --- |
| **Gestational age at birth**  | **Postmenstrual age** | **Chronologic age** |
| 22a\* | 31 | 9 |
| 23a\* | 31 | 8 |
| 24\* | 31 | 7 |
| 25\* | 31 | 6 |
| 26 | 31 | 5 |
| 27 | 31 | 4 |
| 28 | 32 | 4 |
| 29 | 33 | 4 |
| 30 or more | 34 | 4 |
|  |  |  |

a This guideline should be considered tentative rather than evidence-based for 22-to-23-week infants owing to the small number of survivors in these gestational age categories.

**\***Some practitioners have advocated for earlier screening on the basis of speculation that treatable aggressive posterior ROP (AP-ROP) could occur before 31 weeks postmenstrual age. AP-ROP is a severe form of ROP that is characterized by rapid progression to advanced states in posterior ROP.

**REFERENCE:ROP Screening Policy Statement #2.** Based upon Reynolds JD, Dobson V, Quinn GE, et al. CRYO-ROP and LIGHT-ROP Cooperative Groups. Evidence-Based Screening Criteria for Retinopathy of Prematurity: Natural History Data from the CRYO-ROP and LIGHT-ROP Studies. *Arch Ophthalmol.* 2002; 120 (11): 1470-1476.

**[Table 3. Follow-up schedule for ROP exams](#Table_3)**

The examining ophthalmologist should use retinal findings as classified by ICROP[[4]](#footnote-4) to determine the timing of the follow-up examinations.

* 1 week or less
	+ Zone I: Immature vascularization, no ROP
	+ Zone I: Stage 1 or 2 ROP
		- **NOTE IN PS:** Zone I, Stage 3 requires treatment, not observation
	+ Immature retina extends into posterior zone I, near the boundary of zone –zone II.
	+ Suspected presence of AP-ROP (aggressive posterior ROP)
	+ After laser photocoagulation or anti-VEGF injection to ensure that there is no need for additional laser treatment in areas where ablative treatment was not complete or additional anti-VEGF injection.
* 1 to 2 weeks
	+ Posterior zone II: Immature vascularization
	+ Zone II, Stage 2 ROP
	+ Zone I: Unequivocally regressing ROP
* 2 weeks
	+ Zone II: Stage 1 ROP
	+ Zone II: no ROP, immature vascularization
	+ Zone II: Unequivocally regressing ROP
* 2 to 3 weeks
	+ Zone III: Stage 1 or 2 ROP
	+ Zone III: Regressing ROP

**REFERENCE**:**ROP Screening Policy Statement #4**. Based on Reynolds JD, Dobson V, Quinn GE, et al. CRYO-ROP and LIGHT-ROP Cooperative Groups. Evidence-Based Screening Criteria for Retinopathy of Prematurity: Natural History Data from the CRYO-ROP and LIGHT-ROP Studies. *Arch Ophthalmol.* 2002; 120 (11): 1470-1476.

# **Table 4. When to treat ROP**

* The presence of plus disease in zones I or II suggests that peripheral ablation, rather than observation, is appropriate.\*
	+ Plus disease is defined as abnormal dilatation and tortuosity of the posterior retinal blood vessels in 2 or more quadrants of the retina meeting or exceeding the degree of abnormality represented in reference photographs
	+ The presence of plus disease rather than the number of clock hours of disease, is the better determining factor in recommending ablative treatment.
* Treatment should be initiated for the following retinal findings that characterize Type 1 ROP:
	+ Zone I ROP: any stage with plus disease
	+ Zone I ROP: stage 3, no plus disease
	+ Zone II ROP: stage 2 or 3 with plus disease
* Treatment should generally be accomplished, when possible, within 72 hours of determination of treatable disease to minimize the risk of retinal detachment.
* Consideration may be given to treatment of infants with zone I stage 3+ ROP with intravitreal injection of bevacizumab.#
	+ Bevacizumab and other anti-VEGF substances are not approved by the US Food and Drug Administration for the treatment of ROP.
	+ Treatment should only be administered after obtaining detailed informed consent, because there remain unanswered questions involving dosage, timing, safety, and visual and systemic outcomes. Studies have yielded contrary findings on the increased incidence of neurodevelopmental problems, including severe cerebral palsy, hearing loss, and bilateral blindness.
	+ Infants treated with bevacizumab should be monitored closelyuntil at least 65 weeks postmenstrual age
	+ Longer follow-up is required because recurrence occurs considerably later (16 ± 4.6 weeks vs 6.2 ± 5.7 weeks) than after laser therapy. There are reports of recurrence requiring retreatment as late as 65 to 70 weeks postmenstrual age.
	+ The timeframe of highest disease reactivation is between 45 and 55 weeks.
* Follow up is recommended in 3 to 7 days after laser photocoagulation or anti-VEGF injection to ensure that there is no need for additional laser treatment in areas where ablative treatment was not complete or for additional anti-VEGF injection.

**REFERENCE:ROP Screening Policy Statement #4 based upon:**

\* Early Treatment for Retinopathy of Prematurity Cooperative Group. Revised Indications for the Treatment of Retinopathy of Prematurity. Results of the Early Treatment for Retinopathy of Prematurity Randomized Trial. *Arch Ophthalmol.* 2003; 121:1684-1694.

* # Mintz-Hittner HA, Kennedy KA, Chuang AZ; BEAT-ROP Cooperative Group. Efficacy of intravitreal bevacizumab for stage 3+ retinopathy of prematurity. *N Engl J Med*. 2011; 364(7):603–615.

# **Table 5. When to stop ROP screening**

**Per the Policy Statement, one exam is sufficient only if it unequivocally shows the retina to be fully vascularized in both eyes.**

The conclusion of acute-retinal-screening examinations should be based on age and retinal ophthalmoscopic findings. Findings that suggest that examinations can be terminated include:

* Full retinal vascularization in close proximity to the ora serrata for 360°--that is, the normal distance found in mature retina between the end of vascularization and the ora serrata.
* Zone III retinal vascularization attained without previous zone I or II ROP
	+ If there is examiner doubt about the zone or if the postmenstrual age is less than 35 weeks, confirmatory examinations may be warranted.
* Postmenstrual age of 45 weeks: No type 1 ROP or worse is present, and no anti-VEGF treatment
	+ Type 1 ROP disease (previously called “pretheshold”) defined as:
		- Stage 3 ROP in zone II
		- Any ROP in zone I
* Postmenstrual age of 65 weeks: Infants treated with anti-VEGF
	+ Follow closely until at least 65 weeks postmenstrual age
	+ Particularly close follow-up is needed during the time of highest risk for disease reactivation (45 to 55 weeks PMA)
	+ Care must be taken to be sure that there is no abnormal vascular tissue present that is capable of reactivation and progression in Zone II or III
	+ Full retinal vascularization should be the criterion for all infants treated solely with anti-VEGF medication.
	+ Full retinal vascularization is not always achieved in infants treated with anti-VEGF alone.
	+ If there is not full retinal vascularization at 65 weeks PMA, rely upon prolonged observation, clinical judgment, and evolving criteria for termination of exams or a need for further treatment.
* Regression of ROP (see ICROP)
	+ Care must be taken to be sure that there is no abnormal vascular tissue present that is capable of reactivation and progression in zone II or III.

**REFERENCE:ROP Screening Policy Statement # 4.** Based upon Reynolds JD, Dobson V, Quinn GE, et al. CRYO-ROP and LIGHT-ROP Cooperative Groups. Evidence-Based Screening Criteria for Retinopathy of Prematurity: Natural History Data From the CRYO-ROP and LIGHT-ROP.*Arch Ophthalmol.* 2002; 120 (11): 1470-1476.

# **ROP Tracking List**

NOTE: To use as an Excel document, click on the list, choose “Worksheet Object” and then “Open.”



# **Consent for laser surgery to treat ROP (retinopathy of prematurity)**

Your baby has a condition of the retina (the back of the eye) called ROP. When a baby is born prematurely (too early), the retina has not had time to finish forming. After the premature birth, the blood vessels at the back of the eye stop growing. Soon the eye starts to make a chemical called VEGF (vascular endothelial growth factor). This chemical makes the blood vessels start growing again.

But these are not normal blood vessels. These abnormal blood vessels can bleed. They can also pull (detach) the retina away from its normal position. This is called an RD (retinal detachment), and it can cause blindness. This document gives information about the types of treatment. It also explains what happens if the baby does not get treatment for ROP.

**Ophthalmologists (eye surgeons) can treat ROP.**

Ophthalmologists have been treating ROP with laser surgery for many years. This type of laser surgery is called PRP (pan-retinal photocoagulation). The laser stops the eye from making more of the VEGF chemical. The abnormal blood vessels usually stop growing, the retina stays attached, and the central vision is good. Laser works for most babies.

But some babies are too sick to have surgery or anesthesia. In other babies, the abnormal blood vessels are too far back in the eye to use the laser safely. Other parts of the eye or blood in the eye may block the path to the abnormal blood vessels. Ophthalmologists can inject a medicine in the baby’s eye to treat ROP.This is called an intravitreal injection. The medicine stops the eye from making the VEGF chemical. It is called an anti-VEGF medicine.

The goal of laser surgery is to keep the retina attached and save the baby’s vision.Central vision may be good, but the baby will lose some side vision. The laser surgery does not work on every baby. Some babies need more than one laser surgery. Some babies lose vision or go blind even if they have the laser surgery. Sometimes, the abnormal vessels keep growing after laser surgery. These abnormal blood vessels pull the retina out of its normal position and cause an RD. The baby will need other types of surgery to treat the RD.

Your baby could have very poor vision or go blind if the ROP is not treated. Your baby cannot choose whether to have treatment. You need to decide if your baby will get treatment for ROP. You have the legal right to choose for your baby. Because you are an adult, you can refuse (say no) to treatment to save your own vision or your own life.

Your ophthalmologist has a legal duty to treat the baby. If you decide not to treat the ROP, your ophthalmologist must talk to other doctors and child protective services about your choice.

**This laser surgery has risks and can cause problems.**

There are risks with every surgery. These risks can cause vision loss or blindness. Here are some common or serious ones:

* The laser surgery might not stop the ROP.
* The ROP can come back again. The baby may need another laser surgery to treat the ROP.
* Your baby could lose vision or go blind.
* Anesthesia can cause heart or breathing problems, or death
* The laser surgery could cause other eye problems:
	+ Loss of side (peripheral) vision
	+ Damage to the retina: RD, fold in the retina, dragging or scarring of the macula (center of the retina)
	+ Bleeding in the eye (vitreous hemorrhage)
	+ High eye pressure (glaucoma)
	+ Low eye pressure (hypotony)
	+ Burns to the cornea (clear covering of the front of the eye)
	+ Clouding or scarring of the cornea
	+ Damage to the iris (colored part of the eye)
	+ Eyes that look in different directions (strabismus)
	+ Need for very thick glasses
	+ Bigger eye (enlargement)
	+ Smaller eye (shrinkage)

**Consent**. By signing below, you consent (agree) that:

* You read this informed consent form, or someone read it to you.
* You understand the information in this form.
* The ophthalmologist or staff offered you a copy of this form.
* You are aware that the baby may lose vision or go blind.
* You are aware that the baby may need another surgery.
* The ophthalmologist or staff answered your questions about laser surgery for ROP.
* You understand that it is your right to refuse this treatment for your baby. You also understand that if you do refuse the treatment, the ophthalmologist must ask other doctors or child protective services to talk to you about your decision.
* You agree to the laser surgery.

**I want the ophthalmologist to treat my baby with laser surgery on:**

* **\_\_\_\_\_\_\_ the right eye**
* **\_\_\_\_\_\_\_ the left eye**
* **\_\_\_\_\_\_\_ both eyes.**

Patient (or person authorized to sign for patient) Date

# **Consentimiento para cirugía láser para el tratamiento de la ROP (retinopatía de la prematurez)**

Su bebé tiene una condición de la retina (la parte posterior del ojo) conocida como ROP. Cuando nace un bebé prematuro (antes de tiempo), la retina no ha tenido tiempo de acabar de formarse. Después de un nacimiento prematuro, los vasos sanguíneos en la parte posterior del ojo dejan de crecer. Muy pronto el ojo comienza a producir una sustancia química conocida como VEGF (factor de crecimiento de la vasculatura endotelial). Esta sustancia química hace que los vasos sanguíneos comiencen a crecer de nuevo.

Sin embargo, estos no son vasos sanguíneos normales. Son vasos sanguíneos anormales que pueden sangrar. También pueden halar (desprender) la retina de su posición normal. Esto se conoce como DR (desprendimiento de retina) y puede producir ceguera. Este documento ofrece información acerca de los tipos de tratamiento. Explica también lo que ocurre si no se trata al bebé para la ROP.

**Los oftalmólogos (cirujanos de los ojos) pueden tratar la ROP.**

Los oftalmólogos han venido tratando la ROP con cirugía láser desde hace muchos años. Este tipo de cirugía láser se llama PRP (fotocoagulación panretiniana, por su abreviatura en inglés). El láser detiene la producción de la sustancia química VEGF en el ojo. En la mayoría de los casos, los vasos sanguíneos anormales dejan de crecer, la retina permanece adherida y la visión central es buena. El láser es un buen tratamiento para la mayoría de los bebés.

Pero algunos bebés están demasiado enfermos para ser tratados con cirugía o para recibir anestesia. En otros bebés, los vasos sanguíneos anormales están demasiado atrás en el ojo para poder utilizar el láser con seguridad. Es posible que otras partes del ojo o la sangre que puede haber en el ojo bloqueen el paso del láser para alcanzar los vasos sanguíneos anormales. Los oftalmólogos pueden inyectar un medicamento en el ojo del bebé para tratar la ROP.Esta técnica se conoce como inyección intravítrea. El medicamento impide que el ojo siga produciendo la sustancia VEGF y se conoce como medicamento anti-VEGF.

El objetivo de la inyección es mantener la retina adherida y salvar la visión del bebé.La visión central puede ser buena pero el bebé puede perder parte de la visión lateral. La cirugía láser no da resultado en todos los bebés. Algunos requieren más de una cirugía láser. Algunos bebés pierden visión o quedan ciegos aún si se les ha practicado cirugía láser. A veces, los vasos anormales siguen creciendo después de la cirugía, estos vasos sanguíneos anormales halan la retina levantándola de su posición normal y producen lo que se conoce como DR. El bebé requerirá otros tipos de cirugía para tratar el DR.

Su bebé podría terminar con una visión muy baja o quedar totalmente ciego si la ROP no se trata a tiempo. Su bebé no está en capacidad de decidir si quiere o no el tratamiento. Será usted quien decida si su bebé recibe o no el tratamiento para la ROP. Tiene el derecho legal de elegir a nombre de su bebé. Debido a que usted es una persona adulta, puede negarse (puede decir que no) al tratamiento para salvar su propia visión o su propia vida.

Su oftalmólogo tiene el deber legal de tratar al bebé. Si usted decide no tratar la ROP del bebé, su oftalmólogo deberá hablar con otros médicos y con los servicios de protección del menor, acerca de su decisión.

**La cirugía láser puede causar los siguientes problemas.**

Hay riesgos con todas las inyecciones y con todos los medicamentos. Estos riesgos pueden producir pérdida de visión o ceguera. Los siguientes son algunos de los problemas más comunes o más graves:

* La cirugía láser podría no detener el desarrollo de la ROP.
* La ROP puede reiniciarse más adelante. Es posible que el bebé requiera otra cirugía con láser para tratar la ROP.
* Su bebé podría perder visión o quedar ciego.
* La anestesia puede producir problemas cardiacos o respiratorios o la muerte
* La cirugía láser podría causar otros problemas oculares:
	+ Pérdida de visión lateral (periférica)
	+ Daño a la retina: DR, un pliegue en la retina, arrastre o cicatrización de la mácula (centro de la retina)
	+ Sangrado dentro del ojo (hemorragia vítrea)
	+ Alta presión dentro del ojo (glaucoma)
	+ Baja presión dentro del ojo (hipotonía)
	+ Quemaduras en la córnea (la parte transparente que cubre el frente del ojo)
	+ Opacificación o cicatrización de la córnea
	+ Daño al iris (la parte de color del ojo)
	+ Ojos que miran en direcciones distintas (estrabismo)
	+ Necesidad de usar anteojos con lentes muy gruesos
	+ Ojos más grandes (agrandamiento)
	+ Ojos más pequeños (ojos de menor tamaño)

**Consentimiento**. Al firmar al final de este documento, usted da su consentimiento (acepta) y declara que:

* Ha leído este formulario de consentimiento informado, o que alguien que se lo ha leído a usted.
* Entiende la información de este formulario.
* El cirujano o el personal del hospital le han entregado una copia de este formulario.
* Se da cuenta de que su bebé puede perder visión o quedar ciego.
* Se da cuenta de que su bebé puede requerir otra cirugía.
* El cirujano de los ojos o el personal del hospital ha respondido a sus preguntas relacionadas con la inyección para la ROP.
* Entiende que tiene derecho a negarse a aceptar (a decir que no a) este tratamiento para su bebé. Además, entiende que si se niega a aceptar el tratamiento, el oftalmólogo deberá pedir a otros médicos o a personas que trabajen con los servicios de protección del menor que hablen con usted acerca de su decisión.
* Acepta la cirugía láser.

**Deseo que el oftalmólogo le realice a mi bebé una cirugía láser para la ROP en:**

* **\_\_\_\_\_\_\_ el ojo derecho**
* **\_\_\_\_\_\_\_ el ojo izquierdo**
* **\_\_\_\_\_\_\_ ambos ojos.**

Paciente (o persona autorizada para firmar por el paciente) Fecha

# **Consent for injection to treat ROP (retinopathy of prematurity)**

Your baby has a condition of the retina (the back of the eye) called ROP.When a baby is born prematurely (too early), the retina has not had time to finish forming. After the premature birth, the blood vessels at the back of the eye stop growing. Soon the eye starts to make a chemical called VEGF (vascular endothelial growth factor). This chemical makes the blood vessels start growing again.

But these are not normal blood vessels. These abnormal blood vessels can bleed. They can also pull (detach) the retina away from its normal position. This is called an RD (retinal detachment), and it can cause blindness. This document gives information about the types of treatment. It also explains what happens if the baby does not get treatment for ROP.

**Ophthalmologists (eye surgeons) can treat ROP.**

Ophthalmologists have been treating ROP with laser surgery for many years. This type of laser surgery is called PRP (pan-retinal photocoagulation). The laser stops the eye from making more of the VEGF chemical. The abnormal blood vessels usually stop growing, the retina stays attached, and the central vision is good. Laser works for most babies.

But some babies are too sick to have surgery or anesthesia. In other babies, the abnormal blood vessels are too far back in the eye to use the laser safely. Other parts of the eye or blood in the eye may block the path to the abnormal blood vessels.

Ophthalmologists can inject a medicine in the baby’s eye to treat ROP.This is called an intravitreal injection. The medicine stops the eye from making the VEGF chemical. It is called an anti-VEGF medicine. There are three anti-VEGF medicines. They are called Avastin, Eylea, and Lucentis. The ophthalmologist will talk to you about which medicine will be injected.

**The baby may need more treatment.**

The goal of the injection is to keep the retina attached and save the baby’s vision. Some babies lose vision or go blind even if they have the injection. Sometimes, the abnormal vessels keep growing after the injection. The baby may need another injection or laser surgery to stop the abnormal blood vessels. These abnormal blood vessels can pull the retina off the eye and cause an RD. The baby will need other types of surgery to treat the RD. An ophthalmologist will need to keep examining the baby’s eyes for at least six months after the injection to make sure the ROP is gone. You will need to take the baby to the ophthalmologist’s office for these exams after the baby goes home.

Your baby could have very poor vision or go blind if the ROP is not treated. Your baby cannot choose whether to have treatment. You need to decide if your baby will get treatment for ROP. You have the legal right to choose for your baby. Because you are an adult, you can refuse (say no) to treatment to save your own vision or your own life.

Your ophthalmologist has a legal duty to treat the baby. If you decide not to treat the ROP, your ophthalmologist must talk to other doctors and child protective services about your choice.

**Anti-VEGF medicines have not been approved by the FDA to treat children. This is called off-label use.**

The VEGF chemical causes eye diseases in premature babies and adults. Some anti-VEGF medicines have been approved by the FDA (Food and Drug Administration) to treat eye conditions in adults. Ophthalmologists have given anti-VEGF injections to adults for many years. Ophthalmologists started to treat ROP with anti-VEGF medicine in 2006. Ophthalmologists are still studying how well the medicine works to treat ROP and how much medicine to give babies.

**Doctors do not know if the anti-VEGF medicine injected in the eye harms other parts of the baby’s body.**

The medicine gets out of the eye and into the baby’s bloodstream. It reaches the brain, lungs, and kidneys. The brain, lungs, and kidneys need the VEGF chemical to grow. The medicine may harm the brain, lungs, and kidneys.

* Ophthalmologists and neonatologists (baby doctors) are studying babies who get this medicine to see if they have problems with the development of their brain, lungs, and kidneys.
* Premature babies often have problems with their brains, lungs, and kidneys that are caused by being born too soon. They can be very sick. Sick babies may have more problems after injections.
* It is also hard to know if problems that do show up are caused by being premature or from getting the medicine.
* The ophthalmologist will talk to the neonatologist about whether it is safe for your baby to have this medicine.

**This injection has risks and can cause problems.**

There are risks with all injections and with all medicines. These risks can cause vision loss or blindness. Here are some common or serious ones:

* The injection might not stop the ROP.
* The ROP can come back again. The baby may need another injection or laser surgery to treat the ROP.
* Your baby could lose vision or go blind.
* When ROP is treated with laser surgery, the ophthalmologist knows in a few weeks if the ROP will come back. The ophthalmologist may not know for months or years if the ROP will come back after an injection. The ophthalmologist will have to keep checking the eyes for ROP for a very long time after the injection. The baby may need laser surgery if the retina does not grow completely after the injection
* The injection can cause other eye problems:
	+ An eye infection that could cause blindness
	+ RD (detached retina)
	+ Cataracts (clouding of the eye’s lens)
	+ Glaucoma (high eye pressure)
	+ Hypotony (low eye pressure)
	+ Damage to the retina
	+ Damage to the cornea (clear covering of the front of the eye)
	+ Bleeding in the eye
	+ Bright redness in the white part of the eye
	+ Eye irritation and lots of tears
* Adult patients who had these anti-VEGF injections have had heart attack, stroke, or death. The FDA does not know if the medicine caused these problems.

**Consent**. By signing below, you consent (agree) that:

* You read this informed consent form, or someone read it to you.
* You understand the information in this form.
* The eye surgeon or staff offered you a copy of this form.
* You are aware that the baby may lose vision or go blind.
* You are aware that the baby may need another injection or surgery.
* You are aware that the FDA did not approve this medicine for ROP.
* The eye surgeon or staff answered your questions about the injection for ROP.
* You understand that it is your right to refuse (say no) this treatment for your baby. You also understand that if you do refuse the treatment, the ophthalmologist must ask other doctors or child protective services to talk to you about your decision.
* You agree to the injection.

**I want the ophthalmologist to give my baby an injection for ROP in:**

* **\_\_\_\_\_\_\_ the right eye**
* **\_\_\_\_\_\_\_ the left eye**
* **\_\_\_\_\_\_\_ both eyes.**

Patient (or person authorized to sign for patient) Date

# **Consentimiento para aplicación de la inyección como tratamiento de la ROP (retinopatía de la prematurez)**

Su bebé tiene una condición de la retina (la parte posterior del ojo) conocida como ROP.Cuando nace un bebé prematuro (antes de tiempo), la retina no ha tenido tiempo de acabar de formarse. Después de un nacimiento prematuro, los vasos sanguíneos en la parte posterior del ojo dejan de crecer. Muy pronto, el ojo comienza a producir una sustancia química conocida como VEGF (factor de crecimiento de la vasculatura endotelial). Esta sustancia química hace que los vasos sanguíneos comiencen a crecer de nuevo.

Sin embargo, estos no son vasos sanguíneos normales. Son vasos sanguíneos anormales que pueden sangrar. También pueden halar (desprender) la retina de su posición normal. Esto se conoce como DR (desprendimiento de retina) y puede producir ceguera. Este documento ofrece información acerca de los tipos de tratamiento. Explica también lo que ocurre si el (la) bebé no recibe tratamiento para la ROP.

**Los oftalmólogos (cirujanos de los ojos) pueden tratar la ROP.**

Los oftalmólogos han venido utilizando cirugía con láser para tratar la ROP desde hace muchos años. Este tipo de cirugía con láser se llama PRP (fotocoagulación panretiniana, por su abreviatura en inglés). El láser detiene la producción de la sustancia química VEGF en el ojo. En la mayoría de los casos, los vasos sanguíneos anormales dejan de crecer, la retina permanece adherida y la visión central es buena. El láser es un buen tratamiento para la mayoría de los bebés.

Pero algunos bebés están demasiado enfermos para ser tratados con cirugía o para recibir anestesia. En otros bebés, los vasos sanguíneos anormales están demasiado atrás en el ojo para poder utilizar el láser con seguridad. Es posible que otras partes del ojo o la sangre que puede haber en el ojo bloqueen el paso del láser para alcanzar los vasos sanguíneos anormales.

Los oftalmólogos pueden inyectar un medicamento en el ojo de su bebé para tratar la ROP.Esta técnica se conoce como inyección intravítrea. El medicamento impide que el ojo siga produciendo la sustancia VEGF y se conoce como medicamento anti-VEGF. Hay tres medicamentos anti-VEGF. Se llaman Avastin, Eylea y Lucentis. Los oftalmólogos le explicarán cuál de estos medicamentos se inyectará.

**Su bebé puede necesitar más tratamiento.**

El objetivo de la inyección es mantener la retina adherida y salvar la visión de su bebé. Algunos bebés pierden visión o quedan ciegos aún si reciben la inyección. A veces, los vasos anormales siguen creciendo después de la inyección. El (la) bebé puede requerir otra inyección o una cirugía con láser para detener el desarrollo de los vasos sanguíneos anormales. Estos vasos sanguíneos anormales pueden halar de la retina y separarla del ojo ocasionando lo que se conoce como un DR. El (la) bebé requerirá otros tipos de cirugía para tratar el DR. Un oftalmólogo tendrá que examinar constantemente los ojos de su bebé durante al menos seis meses después de la aplicación de la inyección para asegurarse de que ya no haya ROP. Tendrá que llevar a su bebé al consultorio del oftalmólogo para estos exámenes después de que el (la) bebé haya salido del hospital para su casa.

Su bebé podría terminar con una visión muy baja o quedar totalmente ciego(a) si la ROP no se trata a tiempo. Su bebé no está en capacidad de decidir si quiere o no el tratamiento. Será usted quien decida si su bebé recibe o no el tratamiento para la ROP. Tiene el derecho legal de elegir a nombre de su bebé. Debido a que usted es una persona adulta, puede negarse (puede decir que no) al tratamiento para salvar su propia visión o su propia vida.

Su oftalmólogo tiene el deber legal de tratar a su bebé. Si usted decide no tratar la ROP de su bebé, su oftalmólogo deberá hablar con otros médicos y con los servicios de protección del menor, acerca de su decisión.

**Los medicamentos anti-VEGF no han sido aprobados por la FDA para ser utilizados en el tratamiento de los niños. Esto es lo que se conoce como un “uso no incluido en la etiqueta”.**

La sustancia química del VEGF produce enfermedades oculares en los bebés prematuros y en los adultos. Algunos medicamentos anti-VEGF han sido aprobados por la FDA (Administración de Alimentos y Drogas) para tratar afecciones oculares en adultos. Los oftalmólogos han administrado inyecciones anti-VEGF a adultos durante muchos años. Los oftalmólogos comenzaron a tratar la ROP con medicamento anti-VEGF en el 2006. Los oftalmólogos siguen estudiando qué tan bueno es el resultado del medicamento para tratar la ROP y qué cantidad de medicamento debe administrarse a los bebés.

**Los médicos no saben si el medicamento anti-VEGF inyectado en el ojo pueda dañar otras partes del organismo de su bebé.**

La medicina sale del ojo y entra a la circulación sanguínea de su bebé. Llega al cerebro, a los pulmones y a los riñones. El cerebro, los pulmones y los riñones necesitan la sustancia química del VEGF para crecer. El medicamento puede dañar el cerebro, los pulmones y los riñones.

* Los oftalmólogos y los neonatólogos (doctores de los bebés) están estudiando a los bebés que reciben este medicamento para ver si presentan problemas con el desarrollo de su cerebro, sus pulmones y sus riñones.
* Con frecuencia, los bebés prematuros tienen problemas con su cerebro, sus pulmones y sus riñones que son producidos por el nacimiento prematuro. Pueden estar muy enfermos. Los bebés enfermos pueden tener más problemas después de las inyecciones.
* También es difícil saber si los problemas que puedan presentarse sean causados por ser prematuros o por recibir el medicamento.
* EL oftalmólogo hablará con el neonatólogo para saber si es seguro administrar este medicamento a su bebé.

**Esta inyección tiene riesgos y puede ocasionar problemas.**

Hay riesgos con todas las inyecciones y con todos los medicamentos. Estos riesgos pueden producir pérdida de visión o ceguera. Los siguientes son algunos de los problemas más comunes o más graves:

* La inyección podría no detener el desarrollo de la ROP.
* La ROP puede reaparecer más adelante. Es posible que el (la) bebé requiera otra inyección o una cirugía con láser para tratar la ROP.
* Su bebé podría perder visión o quedar ciego(a).
* Cuando se practica cirugía con láser para tratar la ROP, el oftalmólogo sabrá en unas pocas semanas si la ROP puede reactivarse o no. El oftalmólogo tendrá que seguir controlando y examinando periódicamente los ojos de su bebé para detectar la ROP durante mucho tiempo después de la inyección. El (la) bebé podría necesitar cirugía con láser si la retina no crece completamente después de la inyección.
* La inyección puede producir otros problemas oculares:
	+ Una infección ocular que puede causar ceguera
	+ Un RD (desprendimiento de retina)
	+ Cataratas (opacidad del cristalino)
	+ Glaucoma (alta presión dentro del ojo)
	+ Hipotonía (baja presión dentro del ojo)
	+ Daño a la retina
	+ Daño en la córnea (la superficie transparente que cubre el frente del ojo)
	+ Sangrado dentro del ojo
	+ Enrojecimiento intenso en la parte blanca del ojo
	+ Irritación ocular y abundante lagrimación
* Los pacientes adultos que han recibido estas inyecciones anti-VEGF han presentado infartos cardiacos, accidentes cerebrovasculares o muerte. La FDA no sabe si el medicamento ha sido la causa de estos problemas.

**Consentimiento**. Al firmar en la parte inferior de esta página, usted da su consentimiento y confirma que:

* Ha leído este formulario de consentimiento informado, o que alguien que se lo ha leído a usted.
* Entiende la información de este formulario.
* El cirujano o el personal del hospital le han entregado una copia de este formulario.
* Se da cuenta de que el (la) bebé puede perder visión o quedar ciego(a).
* Se da cuenta de que el (la) bebé puede requerir otra inyección o una cirugía.
* Se da cuenta de que la FDA no aprobó este medicamento para la ROP.
* El cirujano de los ojos o el personal del hospital han respondido a sus preguntas relacionadas con la inyección para la ROP.
* Entiende que tiene derecho a negarse a aceptar (a decir que no a) este tratamiento para su bebé. Además, entiende que si se niega a aceptar el tratamiento, el oftalmólogo deberá pedir a otros médicos o a personas que trabajen con los servicios de protección del menor que hablen con usted acerca de su decisión.
* Acepta la inyección.

**Deseo que el oftalmólogo le administre a mi bebé una inyección para la ROP en:**

* **\_\_\_\_\_\_\_ el ojo derecho**
* **\_\_\_\_\_\_\_ el ojo izquierdo**
* **\_\_\_\_\_\_\_ ambos ojos.**

Paciente (o persona autorizada para firmar por el paciente) Fecha

1. Fierson WM. “Screening Examination of Premature Infants for Retinopathy of Prematurity.” Policy Statement (PS) issued by the American Academy of Pediatrics (AAP) Section on Ophthalmology, the American Association of Pediatric Ophthalmology and Strabismus (AAPOS), and the American Association of Certified Orthoptists (AAO). Originally issued in 1997 and updated in 2001, 2005, 2006, and 2018; current version published in *Pediatrics* (Volume 142, Number 6, 2018, at http://pediatrics.aappublications.org/content/early/2018/11/21/peds.20183061. This document refers to recommendations based upon the numbers assigned to them in the PS. [↑](#footnote-ref-1)
2. The International Classification of Retinopathy of Prematurity Revisited. International Committee for the Classification of Retinopathy of Prematurity. *Arch Ophthalmol* 2005. 123: 991-999. Available at <https://jamanetwork.com/journals/jamaophthalmology/fullarticle/417157>. [↑](#footnote-ref-2)
3. Clinical tables based upon Fierson WM. “Screening Examination of Premature Infants for Retinopathy of Prematurity.” Policy Statement (PS) issued by the American Academy of Pediatrics (AAP) Section on Ophthalmology, the American Association of Pediatric Ophthalmology and Strabismus (AAPOS), and the American Association of Certified Orthoptists. Originally issued in 1997 and updated in 2001, 2005, 2006, and 2018; current version published in *Pediatrics* (Volume 142, Number 6, 2018, at <http://pediatrics.aappublications.org/content/early/2018/11/21/peds.20183061>. This document refers to recommendations based upon the numbers assigned to them in the PS. [↑](#footnote-ref-3)
4. The International Classification of Retinopathy of Prematurity Revisited. International Committee for the Classification of Retinopathy of Prematurity. *Arch Ophthalmol* 2005. 123: 991-999. Available at <https://jamanetwork.com/journals/jamaophthalmology/fullarticle/417157>. [↑](#footnote-ref-4)