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**ROP Safety Net Toolkit**

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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.

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# **Procedure 3b. Transfer to Treat**

**Transfer to treat principles**

1. The hospital has a written transfer agreement in place with a hospital that will:
	1. Accept transfers from the NICU and provide ROP treatment within 72 hours.
	2. Admit infants from the outpatient setting for ROP treatment and provide it within 72 hours.
2. The hospital may only transfer an infant who needs ROP treatment if it first:
	1. Obtains the agreement of the treating ophthalmologist at the receiving hospital **AND**
	2. Confirms that treatment will be provided within 72 hours **AND**
	3. Verifies that the receiving hospital has designated someone who is familiar with and understands the ROP Screening Policy Statement to track until the infant meets the end-of-acute screening criteria [[Table 5. When to stop](#_Table_5._)] **AND**
	4. Confirms that the hospital will schedule the first outpatient ROP appointment if the infant is discharged before ROP screening is complete **AND**
	5. Sends the receiving hospital appropriate records and current contact information for the parents.

**Transfer to treat 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 and documents the findings using ICROP [[Table 4. When to treat](#_Table_4._)].
2. The screening ophthalmologist notifies the neonatologist and ROPCs, who update the Hospital [ROP Tracking List](#_ROP_Tracking_List) to indicate that the infant will be transferred for ROP treatment.
3. The screening ophthalmologist contacts the treating ophthalmologist, and conducts and documents a transfer-of-care discussion.
4. The screening ophthalmologist completes and signs the [Transfer for Treatment Letter](#_Letter_to_parent:) or [Spanish transfer to treat letter](#_Carta_a_los) and writes an order for the H-ROPC or NICU nurse to:
	1. Review the letter with the parent, and obtain the parent’s signature.
	2. Give a copy of the signed document to the parent.
	3. Place a copy of the signed document in the infant’s medical record.
5. The neonatologist discusses the need for transfer and treatment with the parents, and clarifies whether the infant will come back to the original hospital after ROP treatment.
6. The neonatologist explicitly addresses the need for ROP treatment within 72 hours in the neonatology discharge summary.
7. The H-ROPC coordinates the transfer:
	1. Contacts the Admissions Nurse at the receiving hospital.
	2. Confirms that a treating ophthalmologist has agreed to provide treatment within 72 hours.
	3. Clarifies whether the infant will be transferred back to the original hospital after treatment.
	4. Verifies that someone will track the ROP care until the infant meets the end-of-acute screening criteria.
	5. Confirms that the hospital will schedule the first outpatient ROP appointment if the infant is discharged before ROP screening is complete.
	6. Sends the receiving hospital all pertinent medical records and current contact information for the parents.
	7. Informs the parent of the name of the treating ophthalmologist.

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

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 with an unstable clinical course, including those requiring cardiorespiratory support and who are believed by their attending pediatrician or neonatologist to be at high risk for ROP.

**REFERENCE: ROP Screening Policy Statement # 3**. 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.

**\*** Infants born before 25 weeks’ gestational age should be considered for earlier screening on the basis of severity of comorbidities (6 weeks’ chronological age, even if before 31 weeks’ postmenstrual age, to enable earlier identification and treatment of aggressive posterior ROP [a severe form of ROP that is characterized by rapid progression to advanced states in posterior ROP] that is more likely to occur in this extremely high-risk population).

**REFERENCE:** **ROP Screening Policy Statement #3.** 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: 1470-1476.

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

The examining ophthalmologist should use retinal findings as classified by [ICROP](https://jamanetwork.com/journals/jamaophthalmology/fullarticle/417157) to determine the timing of the follow-up examinations.

* 1-week or less
	+ Immature vascularization in zone 1—no ROP
	+ Immature retina extends into posterior zone II, near the boundary of zone I
	+ Stage 1 or 2 ROP in zone I
	+ Stage 3 ROP in zone II
	+ The presence or suspected presence of aggressive posterior ROP
	+ Infants treated solely with anti-VEGF medications such as bevacizumab
* 3 to 7 days
	+ After treatment to ensure that there is no need for additional treatment in areas where ablative treatment was not complete.
* 1 to 2 weeks
	+ Immature vascularization in posterior zone II
	+ Stage 2 ROP in zone II
	+ Unequivocally regressing ROP in zone I
* 2 weeks
	+ Stage 1 ROP in zone II
	+ Immature vascularization in zone II—no ROP
	+ Unequivocally regressing ROP in zone II
* 2 to 3 weeks
	+ Stage 1 or 2 ROP in zone III
	+ Regressing ROP in zone III

**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: 1470-1476.

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

* Treatment should be initiated for the following retinal findings:
	+ 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
* 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
* Consideration may be given to treatment of infants with zone I stage 3+ ROP with intravitreal injection of bevacizumab.#
	+ Bevacizumab is 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, visual outcomes, and other long-term effects.
	+ Infants treated with bevacizumab should be monitored weekly until retinal vascularization is complete.
	+ Longer follow-up is required because recurrence occurs considerably later (16 ± 4.6 weeks vs 6.2 ± 5.7 weeks) than after laser therapy.
* Special care must be used in determining the zone of disease.
	+ See page 992 of [ICROP](https://jamanetwork.com/journals/jamaophthalmology/fullarticle/417157) for specific examples of how to identify zone I and II disease by using a 28-diopter lens with binocular indirect ophthalmoscopy.
* The presence of plus disease rather than the number of clock hours of disease may be the determining factor in recommending ablative treatment.
* Treatment should generally be accomplished, when possible, within 72 hours of determination of treatable disease to minimize the risk of retinal detachment.
* Follow up is recommended in 3 to 7 days after treatment to ensure that there is no need for additional treatment in areas where ablative treatment was not complete.

**REFERENCE: ROP Screening Policy Statement #7 and #9 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:

* Zone III retinal vascularization attained without previous zone I or II ROP
	+ If there is examiner doubt about the zone or if the PMA (postmenstrual age) is less than 35 weeks, confirmatory examinations may be warranted.
* 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.
	+ **Per the Policy Statement, this criterion should be used when ROP is treated solely with anti-VEGF medication.**
* Postmenstrual age of 50 weeks and no prethreshold disease or worse ROP is present
	+ Prethreshold disease defined as:
		- Stage 3 ROP in zone II
		- Any ROP in zone I
* Regression of ROP (see [ICROP](#_Appendix_B._))
	+ 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 # 5.** 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.

# **ROP Tracking List**

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



# **Letter to parent: Transfer to treat**

Ophthalmologist: Place on your letterhead

Dear \_\_\_\_\_\_\_\_\_

I am an ophthalmologist (eye physician and surgeon). Your baby’s doctor asked me to examine the baby’s eyes.

**Your baby has a condition of the retina (the back of the eye) called ROP (retinopathy of prematurity).** After a premature birth, the blood vessels at the back of the eye may stop growing. The baby’s body responds by making a chemical called VEGF (vascular endothelial growth factor). This chemical makes new blood vessels start growing.

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.

**Your baby’s blood vessels are abnormal.** Your baby could go blind without treatment. The baby needs to be treated within 72 hours by \_\_\_\_\_\_ [date]. Your baby is being transferred to [\_\_\_\_\_\_\_\_\_] hospital for treatment.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Name of ophthalmologist \_\_\_\_\_ Date

# **Carta a los padres: Transferir para tratar**

Nota para el Oftalmólogo: Copie esto en su papel membretado

Ophthalmologist: Place on your letterhead

Apreciado(a) \_\_\_\_\_\_\_\_\_

Soy oftalmólogo(a) (médico y cirujano de los ojos). El (la) médico que atiende a su bebé me pidió que le examinara los ojos.

**Es posible que su bebé tenga una afección de la retina (la parte de atrás del ojo) que se conoce como ROP (retinopatía de la prematurez).** Después de un nacimiento prematuro, los vasos sanguíneos de la parte posterior del ojo pueden dejar de crecer. El organismo del bebé responde produciendo una sustancia química conocida como VEGF (factor de crecimiento de la vasculatura endotelial). Esta sustancia química hace que comiencen a desarrollarse nuevos vasos sanguíneos.

Pero estos vasos sanguíneos no son normales. Son vasos sanguíneos anormales que pueden sangrar. También halan (desprenden) la retina separándola de su posición normal. Es lo que se conoce como DR (desprendimiento de retina), y puede causar ceguera.

**Los vasos sanguíneos de los ojos de su bebé son anormales.** Su bebé podría quedar ciego(a) a menos que reciba tratamiento. El (la) bebé requiere tratamiento en el término de las siguientes 72 horas, para el \_\_\_\_\_\_ [fecha]. Su bebé será trasferido(a) al hospital [\_\_\_\_\_\_\_\_\_] para tratamiento.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Nombre del oftalmólogo \_\_\_\_\_ Fecha

# **ICROP. Synopsis of International Classification of Retinopathy of Prematurity Revisited (ICROP 2005)[[1]](#footnote-1)**

* UNIFYING PRINCIPLES UNDERLYING CLASSIFICATION
	+ The more posterior the disease and the greater the amount of avascular retinal tissue, the more serious the disease
* REVISIONS incorporated into the 2005 recommendations
	+ Concept of a more virulent retinopathy usually observed in the lowest-birth-weight infants—aggressive posterior ROP (AP-ROP).
	+ Description of an intermediate level of vascular dilatation and tortuosity (pre-plus disease) between normal-appearing posterior pole vasculature and frank plus disease that has marked dilation and tortuosity of the posterior pole vessels
	+ Clarification of the extent of zone I.
* LOCATION (3 zones)
	+ Each zone is centered on the optic disc rather than the macula, in contrast to standard retinal drawings.
	+ Zone I (posterior pole or innermost zone) consists of a circle, the radius of which extends from the center of the optic disc to twice the distance from the center of the optic disc to the center of the macula.
	+ Zone II extends centrifugally from the edge of zone I to the nasal ora serrata (at the 3 o’clock position in the right eye, and the 9 o’clock position in the left eye).
	+ Zone III is the residual crescent of retina anterior to zone II.
		- By convention, zones II and III are considered to be mutually exclusive.
		- ROP should be considered to be in zone II until it can be determined with confidence that the nasal-most 2 clock hours are vascularized to the ora serrata.
* EXTENT OF DISEASE (clock hours)
	+ This is specified as hours of the clock or as 30° sectors. As the observer looks at each eye, the 3 o’clock position is to the right and nasal in the right eye, and temporal in the left eye, and the 9 o’clock position is to the left and temporal in the right eye, and nasal in the left eye.
	+ The boundaries between sectors lie on the clock hour positions; that is, the 12-o’clock sector extends from 12 o’clock to 1 o’clock.
* STAGING OF THE DISEASE: 5 stages
	+ Describes the abnormal vascular response at the junction of the vascularized and avascular retina.
		- Because more than one ROP stage may be present in the same eye, staging for the eye as a whole is determined by the most severe manifestation present. For purposes of recording the complete examination, each stage is defined and the extent of each stage by clock hours or sector is recorded.
	+ Stage 1: Demarcation Line
		- This line is a thin but definite structure that separates the avascular retina anteriorly from the vascularized retina posteriorly.
		- There is abnormal branching or arcading of vessels leading up to the demarcation line that is relatively flat, white, and lies within the plane of the retina.
		- Vascular changes can be apparent prior to the development of the demarcation line, such as dilatation rather than tapering of the peripheral retinal vessels, but these changes are insufficient for the diagnosis of ROP.
	+ Stage 2: Ridge
		- The ridge is the hallmark of stage 2 ROP. It arises in the region of the demarcation, has height and width, and extends above the plane of the retina. The ridge may change from white to pink and vessels may leave the plane of the retina posterior to the ridge to enter it.
		- Small isolated tufts of neovascular tissue lying on the surface of the retina, commonly called “popcorn,” may be seen posterior to this ridge structure. Such lesions do not constitute the fibrovascular growth that is a necessary condition for stage 3.
	+ Stage 3: Extraretinal Fibrovascular Proliferation
		- Extraretinal fibrovascular proliferation or neovascularization extends from the ridge into the vitreous. This extraretinal proliferating tissue is continuous with the posterior aspect of the ridge, causing a ragged appearance as the proliferation becomes more extensive.
		- The severity of a stage 3 lesion can be subdivided into mild, moderate, or severe depending upon the extent of extraretinal fibrovascular tissue infiltrating the vitreous.
	+ Stage 4: Partial Retinal Detachment
		- Stage 4 is divided into extrafoveal (stage 4A) and foveal (stage 4B) partial retinal detachments. Stage 4 retinal detachments are generally concave and most are circumferentially oriented.
		- The extent of retinal detachment depends upon the number of clock hours of fibrovascular traction and their degree of contraction.
		- Typically, retinal detachments begin at the point of fibrovascular attachment to the vascularized retina. In progressive cases, the fibrous tissue continues to contract and the tractional retinal detachment increases in height, extending both anteriorly and posteriorly.
		- Radial detachments and more complex configurations are less common.
	+ Stage 5: Total Retinal Detachment
		- Retinal detachments are generally tractional and may occasionally be exudative.
		- They are usually funnel shaped. The configuration of the funnel itself permits a subdivision of this stage. The funnel is divided into anterior and posterior parts.
			* When open both anteriorly and posteriorly, the detachment generally has a concave configuration and extends to the optic disc.
			* The funnel can be narrow in both its anterior and posterior aspects with the detached retina located just behind the lens.
			* The funnel can be open anteriorly but narrowed posteriorly (less common).
			* The funnel can be narrow anteriorly and open posteriorly (least common).
* PLUS DISEASE
	+ The above stages focus on the changes at the leading edge of the abnormally developing retinal vasculature.
	+ Additional signs indicating the severity of active ROP have been referred to as “plus” disease. These include:
		- Increased venous dilatation and arteriolar tortuosity of the posterior retinal vessels
		- Iris vascular engorgement
		- Poor pupillary dilatation (rigid pupil)
		- Vitreous haze.
	+ The definition of plus disease has been refined to define the minimum amount of vascular dilatation and tortuosity using “standard” photographs and the number of quadrants involved.
	+ A + symbol is added to the ROP stage number to designate the presence of plus disease.
		- Stage 2 ROP combined with posterior vascular dilatation and tortuosity would be written “stage 2+ ROP.”
* PRE-PLUS DISEASE
	+ ROP activity indicated by abnormal dilatation and tortuosity of the posterior pole vessels. Plus disease is the severe form of this vascular abnormality.
	+ Pre-plus disease is defined as vascular abnormalities of the posterior pole that are insufficient for the diagnosis of plus disease but that demonstrate more arterial tortuosity and more venous dilatation than normal.
	+ Over time, the vessel abnormalities of pre-plus may progress to frank plus disease as the vessels dilate and become more tortuous.
	+ Note pre-plus after the stage: “stage 2 with pre-plus disease.”
* AGGRESSIVE POSTERIOR ROP
	+ This is an uncommon, rapidly progressing form designated AP-ROP. **If untreated, it usually progresses to stage 5 ROP.**
	+ It is characterized by:
		- Posterior location
		- Prominence of plus disease
		- Ill-defined nature of the retinopathy.
	+ Most common in zone I, but may occur in posterior zone II
	+ Development and distinguishing features
		- Early on, posterior pole vessels show increased dilation and tortuosity in all 4 quadrants that is out of proportion to the peripheral retinopathy
		- The vascular changes progress rapidly
		- Shunting occurs from vessel to vessel within the retina and not solely at the junction between vascular and avascular retina
		- Often difficult to distinguish between arterioles and venules because both have significant dilation and tortuosity
		- May be hemorrhages between vascularized and avascular retina
		- Does not progress through the classic stages 1 to 3
		- May appear as only a flat network of neovascularization at the deceptively featureless junction between vascularized and nonvascularized retina and may be easily overlooked
		- Typically extends circumferentially and is often accompanied by a circumferential vessel
		- Performing indirect ophthalmoscopy with a 20-D condensing lens instead of a 25- or 28-D lens may help to distinguish the deceptively featureless neovascularization
	+ Previously referred to as “type II ROP” and “Rush disease.” Aggressive, posterior ROP more accurate. Diagnosis can be made on a single visit, does not require evaluation over time.
* REGRESSION OF ROP
	+ Most ROP regresses spontaneously by a process of involution or evolution from a vascoproliferative phase to a fibrotic phase
	+ One of the first signs of stabilization of the acute phase of ROP is the failure of the retinopathy to progress to the next stage.
	+ Morphological signs of regression
		- Occurs largely at the junction of vascular and avascular retina as retinal vascularization advances peripherally
		- On serial examinations, the anteroposterior location of retinopathy may change from zone I to zone II or from zone II to zone III.
		- The ridge may change in color from salmon pink to white.
	+ Involutional sequelae of ROP
		- Peripheral changes
			* Vascular
				+ Failure of peripheral, retinal vascularization
				+ Abnormal, nondichotomous branching of the retinal vessels
				+ Vascular arcades with circumferential interconnection
				+ Telangiectatic vessels
			* Retinal
				+ Pigmentary changes
				+ Vitreoretinal interface changes
				+ Thin retina
				+ Peripheral folds
				+ Vitreous membranes with or without attachment to retina
				+ Lattice-like degeneration
				+ Retinal breaks
				+ Traction-rhegmatogenous retinal detachment
		- Posterior changes
			* Vascular
				+ Vascular tortuosity
				+ Straightening of blood vessels in temporal arcade
				+ Decrease in angle of insertion of major temporal arcade
			* Retinal
				+ Pigmentary changes
				+ Distortion and ectopia of macula
				+ Stretching and folding of retina in macular region leading to periphery
				+ Vitreoretinal interface changes
				+ Vitreous membranes
				+ Dragging of retina over optic disc
				+ Traction-rhegmatogenous retinal detachment
			* The more severe the acute phase of the retinopathy, the more likely involutional changes will be severe as the disease enters what was formerly called the “cicatricial phase.”
1. 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-1)