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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.

**Version 2/14/19**

# **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](#_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 to treat letter](#_Consent_for_laser) or [Spanish Transfer to treat letter](#_ICROP._Synopsis_of) 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)[[1]](#footnote-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 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[[2]](#footnote-2) 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.”



# **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

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. 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)