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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 1a. Tracking ROP care of hospitalized infants**

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

**Tracking principles for hospitalized infants**

1. The ophthalmologist is personally involved in the tracking.
2. The hospital has an ROP coordinator (H-ROPC) who:
   1. 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.
3. Hospitalized infants are tracked by at least two ROP team members:
   1. The hospital ROP coordinator (H-ROPC) **AND**
   2. The office ROP coordinator (O-ROPC) for each ophthalmologist or practice currently providing care.
4. There is only one Master Hospital [ROP Tracking List](#_ROP_Tracking_List) of hospitalized infants who need ROP care, and it is kept by the H-ROPC, who sends a copy to the O-ROPC **at least once a week.**
   1. The Hospital ROP Tracking List contains the following information for each ROP exam and treatment:
      1. Birth information: Infant’s name, date of birth, gestational age at birth, birth weight, and medical record number.
      2. Exam information: Postmenstrual age (gestational age + chronological age), date of exam or treatment, ROP status, next exam (given as both an interval and an approximate date), discharge/transfer date, and date when the infant met the conclusion of acute-phase-screening criteria.
5. The H-ROPC and O-ROPC compare the updated Master Hospital ROP Tracking List with the prior week’s list **at least once a week**, and contact the neonatologist and ophthalmologist about any missed, cancelled, or rescheduled ROP exams.
6. Each infant who meets the criteria for ROP screening is tracked until he meets the end-of-acute screening criteria [[Table 5. When to stop ROP](#_Table_5.__1)].

**Tracking process**

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

1. The neonatologist identifies new infants who meet screening criteria [[Table 1. Who to screen](#_Table_1._Which_1)] and indicates when the initial ROP exam should take place [[Table 2. When to start](#_Table_2._When)].
2. The neonatologist instructs the hospital ROP coordinator (H-ROPC) to add the infant’s name and date of initial exam to the Master Hospital [ROP Tracking List](#_ROP_Tracking_List).
3. The H-ROPC contacts the office ROPC (O-ROPC) to schedule the initial exam.
4. The O-ROPC adds the infant to the Hospital ROP Tracking List and begins tracking when the H-ROPC requests:
   1. The initial ROP exam with a screening ophthalmologist or
   2. A consultation with a treating ophthalmologist to determine if treatment is needed [[Table 4. When to treat](#_Table_4._)].
5. The H-ROPC and O-ROPC update the current Hospital ROP Tracking List:
   1. After each exam:
      1. The screening ophthalmologist informs both the ROPCs of the results of the ROP exam and the interval **and** approximate date of the next exam (e.g., next ROP exam in two weeks on approximately 9/25/19).
      2. The ROPCs compare the scheduled follow-up interval to that recommended in the ROP Screening Policy Statement (PS) [[Table 3. Follow-up exams](#_Table_3._)] and contact the ophthalmologist if the interval is longer than the one indicated by the PS and/or longer than 3 weeks since the last exam.
   2. When treatment is needed:
      1. The screening ophthalmologist informs both the ROPCs that treatment might be needed, and contacts the treating ophthalmologist to conduct the transfer-of-care discussion.
      2. The H-ROPC contacts the O-ROPC for the treating ophthalmologist and schedules an exam to determine if treatment is needed.
   3. After treatment:
      1. The treating ophthalmologist informs both ROPCs of the type of treatment and the interval **and** approximate date of the next exam.
         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 to conduct the transfer-of-care discussion.
      2. The ROPCs compare the scheduled follow-up interval to that recommended in the PS and contact the ophthalmologist if the interval indicated is longer than the one indicated.
   4. When care of the infant is transferred to/from:
      1. Screening and treating ophthalmologist
      2. Hospital-based and outpatient ophthalmologist
      3. Ophthalmologist in one hospital and ophthalmologist in another hospital.
   5. When ROP screening and treatment are complete.
      1. ***Per the Policy Statement, one exam is sufficient only if it unequivocally reveals the retina to be fully vascularized in both eyes.***
      2. The ROPCs continue to track until one of the following conditions has been met and documented:
         1. A treating ophthalmologist has verified that the treatment and follow-up examinations are complete.
         2. Both eyes have met the conclusion-of-acute-screening criteria based upon a binocular indirect ophthalmoscopy exam [[Table 5. When to stop](#_Table_5.__1)].
         3. The current ophthalmologist conducts and documents a transfer-of-care discussion with the ophthalmologist who will take over care.

# **[Table 1. Which infants need an ROP screening examination](#Table_1)[[2]](#footnote-2)**

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[[3]](#footnote-3) 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 Excel document, click on the list, choose “Worksheet Object” and then “Open.”



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/142/6/e20183061>. This document refers to recommendations based upon the numbers assigned to them in the PS. [↑](#footnote-ref-1)
2. 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/142/6/e20183061>. This document refers to recommendations based upon the numbers assigned to them in the PS. [↑](#footnote-ref-2)
3. 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-3)