# SUPPLEMENTAL QUESTIONNAIRE FOR RETINOPATHY OF PREMATURITY (ROP)

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Although relatively infrequent, claims against ophthalmologists arising from the screening for or treatment of ROP can be costly. There have been several published accounts of multi-million dollar awards and settlements, and OMIC's average payout for ROP-related claims is significantly higher than the average settlement for any other ophthalmic activity. A large ROP judgment or settlement against you could have devastating effects on you. **To reduce your risk of ROP-related claims and improve our ability to defend you should one arise, the company has developed underwriting requirements for physicians who render ROP services to infants when they are less than 55 weeks post-menstrual age (gestational age plus postnatal age).**

1 Describe your training and experience specific to ROP, including fellowship training (if any). Date completed

_____ _____

_____ _____

2 OMIC has identified and evaluated an online ROP course that provides clinical considerations critical to ROP management. The course was created by FocusROP. **All OMIC insureds who provide ROP services must successfully complete the FocusROP course.**

Have you completed FocusROP? ☐ Yes Date completed: _____ ☐ No

If no, please contact Linda Nakamura, Risk Management Coordinator, at lnakamura@omic.com or (800) 562-6642, ext. 652, to begin the registration process. OMIC will pay the course fee on your behalf. Completion of this course qualifies insureds for a risk management discount.

3 Which ROP services do you render to infants when they are less than 55 weeks post-menstrual age? *(check all that apply)*

☐ live screening - primary screener ☐ live screening - backup screener

☐ live screening - on rotation ☐ remote screening*

☐ treatment with ☐ laser ☐ anti-VEGF injection ☐ vitrectomy/scleral buckle

*OMIC's professional liability policy extends coverage to ophthalmologists who provide ROP services when they use binocular indirect ophthalmoscopy (BIO) for each exam to determine an infant's ROP status. Ophthalmologists who provide care at hospitals with retinal cameras may use the cameras as part of their documentation of the ROP exam. Coverage also applies to insureds who provide second opinions by reviewing retinal photographs taken in conjunction with another ophthalmologist's BIO exam. However, the policy specifically excludes coverage for "remote screening," a type of telemedicine that uses remote digital fundus imaging (RDFI-TM) instead of a BIO exam to evaluate an infant's ROP status.

**Coverage for "remote screening" is available only by special endorsement** and is subject to review and approval of a supplemental questionnaire and adherence to OMIC's underwriting requirements applicable to remote ROP screening. If you will at times use photos instead of a live exam, you must apply for coverage for remote screening.

4 A. If you are the primary screener, who provides backup? _____

B. If you are the backup screener, who provides primary screening? _____

C. If you screen on rotation, who are the other screeners? _____

D. Do you supervise residents or fellows involved in ROP screening or treatment? ☐ Yes ☐ No

5 Indicate your approximate ROP volume below.

| | Next 12 Months | Last Year | Past 5 years |
|---|---|---|---|
| Screenings - live | _____ | _____ | _____ |
| Screenings - remote | _____ | _____ | _____ |
| Treatments | _____ | _____ | _____ |

Volumes above reflect the number of ☐ infants ☐ exams/treatments

6 For each hospital for which you provide ROP services, please indicate in the chart below the following information:
a) The NICU level. The official definition of NICU designations may vary from state to state. The following descriptions are provided as examples only. ***Please list the highest level that applies.***

| | |
|---|---|
| Level I | Well newborn nursery that provides basic care to low-risk infants. |
| Level II | Special care nursery that provides specialty care to mildly ill infants who are at moderate risk of serious complications but whose problems are expected to resolve quickly and can provide mechanical ventilation for short durations or continuous positive airway pressure. |
| Level III | Neonatal intensive care unit that provides subspecialty intensive care to high-risk infants, including infants with birth weights > 1500 grams and gestational age > 32 weeks. They can perform advanced imaging and provide sustained life support, a full range of respiratory support, and prompt and readily available access to a full range of pediatric medical subspecialists, pediatric surgical subspecialists, pediatric anesthesiologists, and pediatric ophthalmologists. |
| Level IV | Regional NICU that provides the highest level of neonatal care. These facilities are located within institutions that can provide surgical repair of complex congenital or acquired conditions. A full range of pediatric medical subspecialists, pediatric surgical subspecialists, and pediatric anesthesiologists are on site. |

b) The approximate number of screenings and/or treatments you performed at this hospital within the past year.
c) Whether the hospital has a written protocol assigning responsibility for each task in the ROP process. OMIC has developed sample protocols for both hospital- and office-based screening. The OMIC ROP Safety Net is available at www.omic.com/rop-safety-net. Please contact OMIC's Risk Management Hotline for assistance at (800) 562-6642, option 4.
d) Whether the hospital maintains an ROP tracking system.
e) Whether the hospital has a qualified ROP coordinator (ROPC). An ROPC is a person with clinical knowledge and understanding of ROP, such as a NICU nurse or neonatologist, who assumes the responsibility for tracking infants until they meet end-of-screening/treating criteria (per the Policy Statement) or have been transferred to the care of an ophthalmologist in the office or another hospital. The ROPC should be someone other than the screening ophthalmologist. Qualifications and duties of a Hospital ROPC are described in the OMIC ROP Safety Net.
f) Whether you are notified by the neonatologist or ROPC prior to discharge or transfer of infants who meet screening or treatment criteria so that you can make and document follow-up recommendations.
g) Whether the hospital has a treating ophthalmologist with staff privileges (OS) or a formal standing transfer agreement (STA) with a hospital with an ophthalmologist who can treat the infant.

| Hospital | (a) NICU level | (b) Screened (#) | (b) Treated (#) | (c) Written protocol (Y/N) | (d) Tracking system (Y/N) | (e) ROPC (Y/N) | (f) Discharge/ transfer notification (Y/N) | (g) Treating MD on staff or by transfer (OS/STA) |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |

*Continue on a separate page, if needed.*

h) Please explain your "no" responses for Question 6c-g: ☐ not applicable (all responses are "yes")

_____

_____

_____

7 Do you have a written protocol for office-based ROP services? ☐ yes ☐ no ☐ n/a – do not provide office-based services

***If yes,*** when was your protocol last updated (month/year)? _____

OMIC has developed sample protocols for both hospital- and office-based screening. The OMIC ROP Safety Net is available at www.omic.com/rop-safety-net. For assistance, contact OMIC's Risk Management Hotline at (800) 562-6642, option 4.

8 Are office staff members who answer phones:

a) Aware that you evaluate and/or treat premature babies with ROP? ☐ Yes ☐ No

b) Aware of the consequences of a delay in screening or treatment? ☐ Yes ☐ No

c) Trained how to identify calls about patients who might need ROP screening or treatment so they can be scheduled appropriately (i.e., do they ask if the infant is premature)? ☐ Yes ☐ No

A sample Office ROP Contact Form is available in OMIC's ROP Safety Net.

9 Guidelines for treatment of ROP are evolving. Many questions are currently being studied and debated about intravitreal anti-VEGF (IVAV) injections, such as Avastin™ (bevacizumab) or Lucentis™ (ranibizumab), as primary or salvage therapy for retinopathy of prematurity. These issues include agent, dosage, timing, safety, and visual and systemic outcomes. There is not yet enough data to develop consensus recommendations. Ophthalmologists who treat ROP with anti-VEGF injections need to remain extremely vigilant. OMIC addresses these concerns and provides risk management recommendations in "Anti-VEGF Intravitreal Injections for ROP: Risk Management Analysis and Recommendations," available online at www.omic.com/rop-intravitreal-anti-vegf-injections-ris-management-recommendations.

Infants treated for ROP with IVAV must be followed closely until at least 65 weeks postmenstrual age (PMA). At 65 weeks PMA, screening may end if either of these endpoints has been reached:
• Full vascularization in close proximity to the ora serrata for 360°, **OR**
• The avascular retina has been successfully treated with laser (e.g., no skip areas)

Use professional judgment on continued monitoring in the following circumstances if no treatment endpoint has been reached at 65 weeks PMA:
o Low-grade disease that is clearly and slowly improving
o Stage 1 disease that is unchanged for 2 months
o No disease, no ROP, but incomplete vascularization
o Infants with DNR orders

Please initial to confirm your understanding and agreement to abide by these requirements. Initial: _____

Do you ever administer IVAV injections for the treatment of ROP? ☐ Yes ☐ No ☐ n/a - do not treat

**If yes:**
a) In approximately what percentage of treatments are IVAV injections administered? _____%
b) Under what circumstances do you administer IVAV? (check all that apply)

☐ Failed laser treatment
☐ Patient cannot tolerate anesthesia
☐ Under an IRB-approved protocol
☐ Aggressive-posterior ROP (Zone I or posterior Zone II)
☐ Visibility impaired by blood or structures
☐ Other (specify:_____)

c) OMIC has developed a procedure-specific consent form for IVAV treatment of ROP, available at www.omic.com/rop-intravitreal-anti-vegf-injections.
Do you use OMIC's sample consent form? ☐ Yes ☐ No
***If no***, please submit your consent form for IVAV treatment of ROP.

**To be eligible for coverage of ROP services, you must comply with the following underwriting requirements (items 10 – 19, below). Please initial each item to confirm your understanding and agreement to abide by these requirements. Failure to comply with OMIC's underwriting requirements (other than deviations specifically approved by OMIC) or to notify OMIC promptly of changes in your ROP protocol may result in uninsured risk or termination of coverage.**

10 You must **use the International Classification of Retinopathy of Prematurity (ICROP) Revisited** to classify, diagram, and record the retinal findings. ICROP Revisited is published in OMIC's ROP Safety Net, available at www.omic.com/rop-safety-net. Initial: _____

11 **The "Dear Parent" letter** (available in OMIC's ROP Safety Net at www.omic.com/rop-safety-net) **or a similar form must be completed** for each infant examined, and the caregiver should be asked to sign the form, prior to the infant's discharge from the hospital and upon the initial outpatient examination. The handout is intended as a supplement to, and not a replacement for, communication with the caregiver. It serves as an important educational tool to explain the ROP process and the importance of timely follow-up. OMIC believes that use of a handout and associated parent education will help reduce the possibility of missed appointments.

Initial: _____

12 Unless care has been duly transferred to another ophthalmologist as outlined below, you must **screen each infant until both eyes have met the conclusion-of-acute-phase-ROP screening criteria or until a treating ophthalmologist has verified that treatment and all follow-up examinations have been completed** (based upon criteria established in "Screening Examination of Premature Infants for Retinopathy of Prematurity," the Policy Statement issued by the American Academy of Pediatrics (AAP) Section on Ophthalmology, American Academy of Ophthalmology (AAO), American Association for Pediatric Ophthalmology and Strabismus (AAPOS), and American Association of Certified Orthoptists (AACO). Most recently updated in 2018, the Policy Statement is published in *Pediatrics* (http://pediatrics.aappublications.org/content/early/2018/11/21/peds.2018-3061.)

☐ n/a – do not screen Initial: _____

13 The **maximum time interval between exams** must be no longer than 3 weeks (in accordance with the Policy Statement).

☐ n/a – do not screen Initial: _____

14 When referring or transferring care of any infant 55 weeks postmenstrual age or younger to another ophthalmologist (such as from inpatient screener to outpatient screener or from screener to treater), you must **conduct and document a transfer-of-care discussion** with the next ophthalmologist, conveying the urgency of the referral, and ensure that he/she has copies of the patient's previous examinations and has agreed to provide the care in the necessary time frame.

☐ n/a – do not refer or transfer care Initial: _____

15 You must **maintain a system that tracks each infant** from the time of the first visit (whether in the hospital or in the office) until the child has met the end-of-acute screening criteria of the Policy Statement or you have formally transferred care to another ophthalmologist. Studies have shown that redundancy creates safety. To create a "safety net" and minimize the risk of an infant being lost to follow-up, tracking must be done by at least one person in your office and at least one person in the hospital. You must personally be involved in the tracking process.

Your tracking system must include the following elements:

a. Your practice must have an assigned office staff coordinator who is responsible for tracking ROP appointments in the hospital, scheduling ROP appointments in the office, and tracking no-shows. This ROP coordinator must be familiar with the Policy Statement and use it to review the appropriateness of follow-up intervals. Qualifications and duties of an office ROPC are described in OMIC's ROP Safety Net.

b. Your tracking system must be updated each time the baby is evaluated or treated.

c. Your tracking system must be evaluated on a routine basis (at least once a week while infants are actively being screened or treated) to ensure that all follow-up appointments are scheduled and kept.

d. You must indicate the follow-up interval in the office chart. This should be expressed both in terms of time interval and date (e.g. two weeks, around May 2, 2018). The interval must be consistent with the Policy Statement: the longest period is 3 weeks, but many infants will need to be seen sooner than that.

e. The next office appointment must be scheduled *before the caregivers leave the office.*

f. Appointments must be reviewed on a daily basis, and you must be notified immediately of any changes in ROP appointments, including non-shows and cancelled or rescheduled appointments.

g. All follow-up efforts for missed, cancelled, or rescheduled appointments must be documented. (See OMIC's ROP Safety Net for a sample "missed appointment" letter.)

Initial: _____

**The following requirements (16 – 19) apply to hospital-based ROP care** ☐ not applicable (no hospital-based care rendered)

16 You and your office must **track ROP appointments** (see number 15 above). Initial: _____

17 You must **include an ROP consult note** in the infant's hospital chart at the time of each examination or treatment using the terminology of ICROP Revisited.

Initial: _____

18 You must **indicate the follow-up interval** in the hospital chart. This should be expressed both in terms of time interval and date (e.g. two weeks, around May 2, 2018). The interval must be consistent with the Policy Statement: the longest period is 3 weeks, but many infants will need to be seen sooner than that.

Initial: _____

19 You must **personally notify the neonatologist and/or ROP Coordinator and document the recommendation** to begin treatment in the hospital record. If you do not provide treatment, you must conduct and document a transfer of care discussion with the treating ophthalmologist. If the hospital does not have a treating ophthalmologist on staff, you must write an order for an urgent consultation with a treating ophthalmologist so that the infant may receive treatment within 48 to 72 hours, consistent with the Policy Statement. To prevent a delay in treatment, the hospital must have a formal transfer agreement with an area hospital that does provide treatment.

Initial: _____

*OMIC insureds may call the Risk Manager for confidential assistance implementing the Safety Net at (800) 562-6642, extension 641 (option 4 from the main menu).*

"Retinopathy of Prematurity: Case-Based Training" is an online training exercise developed by R.V. Paul Chan, MD, Michael F. Chiang, MD, and Karyn Jonas, RN. This ROP Case Training course, featuring virtual patients who present with ROP along with their clinical history and imaging studies, is available in the Pediatric Ophthalmology Education Center on the AAO web site (http://www.aao.org/clinical-education/pediatric-ophthalmology-education-center).

Please initial the statement below that describes your compliance with the above underwriting requirements:

_____ I have read and currently comply with OMIC's underwriting requirements specific to retinopathy of prematurity (ROP).

_____ I have read and currently comply with OMIC's underwriting requirements specific to retinopathy of prematurity (ROP), with the exception of the following:

| **Item Number** | **Explanation** |
|---|---|
| _____ | _____ |
| _____ | _____ |
| _____ | _____ |

I expect to be in full compliance by _____
*(date)*

_____ _____ _____
*Signature* *Print Name* *Date*