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1. Preface

The Provincial Vision Strategy Task Force was established by the Ministry of Health and Long-Term Care (“the Ministry”) in September 2012. Their purpose was to develop a Vision Strategy to improve quality, access, and system integration of ophthalmology services for the people of Ontario. The Task Force put forth 10 months of highly committed work towards the development of the Vision Strategy, including an evidence-based review of the current state of ophthalmology services in Ontario along with an evaluation of the province’s future patient needs. Through this analysis, a comprehensive, well-informed set of strategic recommendations were developed. These recommendations reflect a patient-centered focus on creating a system of Ophthalmology in Ontario that delivers the highest possible value to Ontarians.

One of the most noticeable opportunities for system improvement arose from the Task Force’s analysis around procedure rates. The Task Force found that wide variation exists in the medical management of retinal diseases, with some LHINs performing up to 4 times more intraocular injections and 6 times more diagnostic tests per 100,000 population than other LHINs. Similarly, wide variation could also be found across LHINs in retina surgical procedure rates.

In an effort to ensure that patients receive equitable services regardless of where they live, the Task Force developed a recommendation for the implementation of an Integrated Retinal Quality Based Procedure (QBP). This QBP would include not only surgical and medical retina procedures but also the associated pharmaceuticals and diagnostic testing. As such, this is the first QBP that integrates the Ontario Drug Benefit Formulary in its care pathways.

The Ministry approved the recommendation and set forth to assemble the Integrated Retinal QBP Clinical Expert Advisory Group (“the Advisory Group”) to lead the development of this QBP.

The content in this document has been developed through collaborative efforts between the Ministry and the Advisory Group. A Methodology Group, consisting of data and coding experts, clinicians and administrators, was also created as a subgroup of the Advisory Group to support the data analysis associated with the development of this Handbook.

Scope of the Handbook

The specific components that the Ministry asked the Advisory Group to consider in developing this Clinical Handbook include:

- Performing a thorough Episode of Care Analysis including:
  - An analysis of the empirical and costing data from CIHI, OCCI, OHIP and ODB by coding, costing and health analytic experts.
  - Analysis of the case mix grouping models.
  - Analysis of the relationship between General Practitioners, General Ophthalmologist, Retina Specialist, Pharmacy and Diagnostics.
- Defining the patient cohorts and the coding methodology.
- Developing Episode of Care Pathways for the relevant patient cohorts.
- Developing performance indicators.
The scope of the work of the Integrated Retinal QBP focuses not only on hospital care but also elements of care that are commonly performed in the community. For example, procedures such as intraocular injections and some diagnostic testing can be performed in ophthalmology clinics and offices.

Given that the Ministry’s QBP funding efforts for 2013/14 focus largely on hospital payment, the Advisory Group was asked to adopt a similar focus with its work on episodes of care. However, given the frequency with which intraocular injections are performed in Ontario the Advisory Group also spent considerable time exploring pathways and developing best practice recommendations towards higher quality care in other aspects of retinal disease management which involve intraocular injection.

All pricing work related to the QBP funding methodology will be led by the Ministry using a standardized approach. This approach will be informed by the content of this Handbook along with the clinical input of the Advisory Group.

The recommended practices outlined in this handbook also provide the basis for assessing standards of care in the management of retinal disease in Ontario. These recommendations can be linked not only to funding mechanisms, but also to other health system measures such as performance measurement and reporting, program planning, and quality improvement activities.

The Advisory Group will revisit the recommended practices and supporting evidence to update this document with relevant new published research at least every two years. In cases where the episode of care models are updated, any policy applications informed by the models will be similarly updated. Consistent with this principle, the Ministry has stated that the QBP models will be reviewed at least every 2 years.

*The template for the Quality-Based Procedures Clinical Handbook and all content in Section 2 (“Purpose”) and Section 3 (“Introduction”) were provided in standard form by the Ministry. All other content was developed by the Advisory Group and project team.*
2. **PURPOSE**

*Provided by the Ministry of Health and Long-Term Care*

This clinical handbook has been created to serve as a compendium of the evidence-based rationale and clinical consensus driving the development of the policy framework and implementation approach for the Integrated Retinal Quality Based Procedure.

This document has been prepared for informational purposes only. This document does not mandate health care providers to provide services in accordance with the recommendations included herein. The recommendations included in this document are not intended to take the place of the professional skill and judgment of health care providers.
3. INTRODUCTION TO QUALITY-BASED PROCEDURES

Provided by the Ministry of Health and Long-Term Care

Historically, a large portion of health service providers’ funding has been grounded on a base annualized funding (global allocation), which is used to maintain day-to-day operations, such as: staff wages & benefits, overhead costs and service/maintenance contracts, and new incremental funding, based on a funding formula, which takes into account demographics and acuity: growth funding targeted at fastest growing communities, hospital type (i.e. small/rural to cover service gaps, academic hospital sites to cover higher cost and acuity).

There needs to be a move to better integrate and align funding mechanisms across sectors to respond to volume and mix of services that meet population need through the pathway of care for patients. By focusing on an enhanced alignment between high quality patient care and funding, reductions in variation in practice across the province can be achieved. The results of such reduction in practice variation facilitate the adoption of best clinical evidence-informed practices, ensuring our patients receive the right care, at the right place and at the right time.

In response to these fiscal challenges, as of April 1, 2012, the Ministry has implemented Health System Funding Reform (HSFR). Over the fiscal years 2012/13 to 2014/15, HSFR will shift much of Ontario’s health care system funding for hospitals and Community Care Access Centres (CCACs) away from the current global funding allocation towards paying for activity and patient outcomes, to further support quality, efficiency and effectiveness in the health care system.

HSFR is predicated on the tenets of Ontario’s Action Plan for Health Care and is aligned with the four core principles of the Excellent Care for All Act (ECFAA):

- Care is organized around the person to support their health;
- Quality and its continuous improvement is a critical goal across the health system;
- Quality of care is supported by the best evidence and standards of care; and
- Payment, policy and planning support quality and efficient use of resources.

HSFR is comprised of three key components:

1. Organizational-Level funding, which will be allocated as base funding using the Health Based Allocation Model (HBAM);
2. Quality-Based Procedure (QBP) funding, which will be allocated for targeted clinical areas based on a “price x volume” approach premised on evidence-based practices and clinical and administrative data; and
3.1 **WHAT ARE WE MOVING TOWARDS?**

Prior to the introduction of HSFR, a significant proportion of hospital funding was allocated through a global funding approach, with specific funding for select provincial programs, wait times services and other targeted activities. A global funding approach may not account for complexity of patients, service levels and costs and may reduce incentives to adopt best practices that result in improved patient outcomes in a cost-effective manner.

Under HSFR, provider funding is based on: the types and quantities of patients providers treat, the services they deliver, the quality of care delivered and patient experience/outcomes. Specifically, QBPs provide incentives to health care providers to become more efficient and effective in their patient management by accepting and adopting best practices that ensure Ontarians get the right care, at the right time and in the right place.

The variations in patient care evident in the global funding approach warrant the move towards a system where ‘money follows the patient” (Figure 1).

Internationally, similar models have been implemented since 1983. As Ontario is the latest leading jurisdictions to move down this path, this puts the province in a unique position to learn from international best practices and pitfalls and create a funding model that is best suited for the province.

Figure 1: The Ontario government is committed to moving towards patient-centred, evidence-informed funding that reflects local population needs and incents delivery of high quality care

<table>
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<tr>
<th>Current</th>
<th>Transition Phase</th>
<th>Future</th>
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<td>- Fragmented system planning</td>
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<td>- Funding not linked to outcomes</td>
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<td>- Does not recognize efficiency, standardization and adoption of best practices</td>
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<td>- Maintains sector specific silos</td>
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3.2 **HOW WILL WE GET THERE?**
The ministry has adopted a multi-year implementation strategy to phase in the HSFR strategy and began to make modest funding shifts beginning April 2012. A three-year outlook has been provided to the field to support planning for upcoming funding policy changes.

The ministry has released a set of tools and guiding documents to further support the field in adopting the funding model changes. For example, a Quality-Based Procedure (QBP) interim list has been published for stakeholder consultation and to promote transparency and sector readiness. The list is intended to encourage providers across the continuum to analyze their service provision and infrastructure in order to improve clinical processes and where necessary, build local capacity. However, as implementation evolves, the interim list will continue to undergo further refinements pending stakeholder feedback and advice from the QBP Clinical Expert Advisory Groups.

The successful transition from the current, ‘provider-centred’ funding model towards a ‘patient-centred model’ will be catalyzed by a number of key enablers and field supports. These enablers translate to actual principles that guide the development of the funding reform implementation strategy related to QBPs. These principles further translate into operational goals and tactical implementation, as presented in Figure 2.

Figure 2: Principles guiding the implementation of funding reform related to Quality-Based Procedures

### Principles for developing QBP implementation strategy
- Cross-Sectoral Pathways
- Evidence-Based
- Balanced Evaluation
- Transparency
- Sector Engagement
- Knowledge Transfer

### Operationalization of principles to tactical implementation (examples)
- Development of best practice patient clinical pathways through clinical expert advisors and evidence-based analyses
- Integrated Quality Based Procedures Scorecard
- Alignment with Quality Improvement Plans
- Publish practice standards and evidence underlying prices for QBPs
- Routine communication and consultation with the field
- Clinical Expert Advisory Groups
- Overall HSFR Governance structure in place that includes key stakeholders
- Technical and clinical engagement sessions
- Applied Learning Strategy/ IDEAS
- Tools and guidance documents
- HSFR Helpline; HSIMI website (repository of HSFR resources)

3.3 **What are Quality-Based Procedures?**
QBPs are clusters of patients with clinically related diagnoses or treatments that have been identified using an evidence-based framework (Figure 3) as providing opportunity for process improvements, clinical redesign, improved patient outcomes, enhanced patient experience and potential cost savings.

The evidence-based framework uses data from the Discharge Abstract Database (DAD), National Ambulatory Care Reporting System (NACRS) and the OHIP database (to access procedure volumes). Additional data was used from the Ontario Case Costing Initiative (OCCI), and Ontario Cost Distribution Methodology (OCDM). In the case of the Integrated Retinal QBP, the framework also used date elements from the Ontario Drug Benefit Program. Evidence such as publications from Canada and other jurisdictions and World Health Organization reports were also used to assist with the patient clusters and the assessment of potential opportunities.

The evidence-based framework assessed patients using five perspectives, as presented in Figure 3. This evidence-based framework has identified QBPs that have the potential to improve quality of care, standardize care delivery across the province, and show increased cost efficiency.

**Figure 3: Evidence-Based Framework**

An evidence and quality-based framework has identified Quality-Based Procedures that have the potential to both improve quality outcomes and reduce costs.

- Does the clinical group contribute to a significant proportion of total costs?
- Is there significant variation across providers in unit costs/volumes/efficiency?
- Is there potential for cost savings or efficiency improvement through more consistent practice?
- How do we pursue quality and improve efficiency?
- Are there potential areas for integration across the care continuum?
- Are there clinical leaders able to champion change in this area?
- Is there data and reporting infrastructure in place?
- Can we leverage other initiatives or reforms related to practice change (e.g., wait times, provincial programs)?
- Is this aligned with Transformation priorities?
- Will this contribute directly to Transformation system redesign?
- Is there a clinical evidence base for an established standard of care and/or care pathway? How strong is the evidence?
- Is costing and utilization information available to inform development of reference costs and pricing?
- What activities have the potential for bundled payments and integrated care?
- Is there variation in clinical outcomes across providers, regions and populations?
- Is there a high degree of observed practice variation across providers or regions in clinical areas where a best practice or standard exists, suggesting such variation is inappropriate?

**Practice Variation**
A demonstrated large practice or outcome variance may represent a significant opportunity to improve patient outcomes by reducing practice variation and focusing on evidence-informed practice. Wide variations in procedure rates or in costs are flags for such practice variation. Ontario has detailed case costing data from many hospitals, as far back as 1991 for all patients discharged from some case costing hospitals, as well as daily utilization and cost data by department, by day and by admission.

**Availability of Evidence**

A significant amount of research has been completed both in Canada and across the world to develop and guide clinical practice. Working with the clinical experts, best practice guidelines and clinical pathways can be developed for these QBPs and appropriate evidence-informed indicators can be established to measure the quality of QBP care and help identify areas for improvement at the provider level and to monitor and evaluate the impact of QBP implementation.

**Feasibility/ Infrastructure for Change**

Clinical leaders play an integral role in this process. Their knowledge of the patients and the care provided or required represents an invaluable component of assessing where improvements can and should be made. Many groups of clinicians have already formed and provided evidence and the rationale for care pathways and evidence-informed practice.

**Cost Impact**

The selected QBP should have as a guide no less than 1,000 cases per year in Ontario and represent at least one per cent of the provincial direct cost budget. While cases that fall below these thresholds may in fact represent improvement opportunity, the resource requirements to implement a QBP may inhibit the effectiveness for such a small patient cluster, even if there are some cost efficiencies to be found. Clinicians may still work on implementing best practices for these patient sub-groups, especially if it aligns with the change in similar groups. However, at this time, there will be no funding implications. The introduction of evidence into agreed-upon practice for a set of patient clusters that demonstrate opportunity as identified by the framework can directly link quality with funding.

**Impact of Transformation**

The selected QBPs must align with the government’s transformational priorities including alignment with the tenets of Ontario’s Action Plan for Health Care. In addition, a natural progression and trajectory to assess a QBP’s impact on transformation would be to begin to look at other patient cohorts (e.g. paediatric patient populations), impact on the transition of care from acute-inpatient to community care setting, significant changes from historical funding models/ approaches, integrated care models etc. QBPs with a lesser cost impact but a large impact on the transformation agenda may still be a high priority for creation and implementation.

**3.4 Opportunities to Improve Retinal Care**
3.5 HOW WILL QBPS ENCOURAGE INNOVATION IN HEALTH CARE DELIVERY?

QBPs encourage innovation in health care delivery by promoting best practices that are based on clinical evidence and best practice recommendations from the Clinical Expert Advisory Groups. The Clinical Expert Advisory Groups are comprised of cross-sector, multi-geographic and multi-disciplinary membership. The panel members leverage their clinical experience and knowledge to define the patient populations and recommend best practices.

Once recommended best practices are defined, these practices are used to understand required resource utilization for the QBPs and further assist in the development of evidence-informed prices. The development of evidence-informed pricing for the QBPs is intended to incent health care providers to adopt best practices in their care delivery models, maximize their efficiency and effectiveness, and engage in process improvements and / or clinical redesign to improve patient outcomes.

Best practice development for the QBPs is intended to promote standardization of care by reducing unexplained variation and ensure the patient gets the right care, at the right place and at the right time. Best practices standards will encourage health service providers to ensure the appropriate resources are focused on the most clinically relevant and cost effective approaches.

QBPs create opportunities for health system change where evidence-informed guidelines and prices can be used as levers to incent providers to:

- Retina procedures account for a large annual provincial hospital service volume as well as a significant annual direct cost to the province (together adding to an estimated $26.8M in direct costs).
- In 2011-12, Lucentis® cost the province’s OD program $464MM.
- Armed with the expertise and knowledge gained from developing the Provincial Vision Strategy report, the members of the Provincial Vision Strategy Task Force will be enthusiastic change agents in the implementation of this QBP.
- In terms of data and reporting structures, retinal surgery wait time data is currently being reported through the Access to Care Wait Time system.

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**Figure 4: Evidence Based Framework for Integrated Retinal QBP**

- It addresses the demographic challenges that Ontario is facing.
- It creates a sustainable system in retinal ophthalmology that is based on quality and evidence-based practice rather than the capacity to provide care.
- It provides an opportunity to integrate health-based programs into a quality-based framework that has not been previously considered (i.e., pharmacare).
- Level one evidence is available on best practice in the care of diabetics as well as on the effectiveness of intravitreal injections in the treatment of AMD.
- Costing information for medical retina and surgical retina procedures is available through the Ontario Case Coding initiative.
- As such, the implementation of the Integrated Retinal Ophthalmology QBP presents an unprecedented bundling opportunity which would, for the first time, incorporate a review of the best practice use of pharmaceuticals from the ODB formulary used for intravitreal injections.

- There is significant practice variation across the province for all components of retinal ophthalmology which evidenced by the standardized procedure rates:
  - Medical retina varies from 0-160 cases per 100,000
  - Surgical retina varies from 0-100 cases per 100,000
  - Injections for AMD vary from 3,523 to 5,038 per 100,000
  - OCT varies from 2,318 to 11,509 per 100,000.
• Adopt best practice standards;

• Re-engineer their clinical processes to improve patient outcomes;

• Improve coding and costing practices;

• Improve integration with services which occur in community clinics as well as with primary care services; and

• Develop innovative care delivery models to enhance the experience of patients.

An integral part of the enhanced focus on quality patient care will be in the development of indicators to allow for the evaluation and monitoring of actual practice and support on-going quality improvement.

4. DESCRIPTION OF RETINAL DISEASE

The retina is a light-sensitive area in the back of the eye. It includes the macula, which is made up of light-sensitive cells that are responsible for sharp, detailed vision. Images are focused onto the retina and then
converted into electrical signals that are sent to the brain for processing. The vitreous body of the eye is a clear gel which fills the cavity between the retina and the lens.

Diseases and conditions affecting the retina, macula (the central portion of the retina), and the vitreous body can lead to blindness or deterioration of vision and may require treatment to preserve vision. Some common retinal diseases include:

- Diabetic Retinopathy
- Age-related Macular Degeneration
- Retinal Tear or Detachment
- Vitreomacular traction, Macular hole and Epi-retinal Membrane

Retinal diseases often require the use of specialized diagnostic testing including Ocular Coherence Tomography (OCT) and/or Intravenous Fluorescein Angiography (IVFA).

Depending on the diagnosis, there may be several treatment options available; these include intraocular injections, laser treatment, and vitreoretinal surgery. Vitreoretinal surgery is usually performed in an ambulatory operating room setting in a hospital or IHF but may be done on an inpatient basis if patient or ocular comorbidity requires this. Laser procedures may be done in an operating room in conjunction with vitreoretinal surgery, in a hospital or IHF outpatient clinic, or occasionally, in an office setting. Intraocular injection may be done in conjunction with vitreoretinal surgery and laser procedures or as a “stand alone” procedure. Most are performed in office ophthalmology clinics, but can also be done in a hospital or IHF.
4.1 DIABETIC RETINOPATHY

Diabetic retinopathy is a term that refers to the retinal changes induced by diabetes. It is subdivided into non-proliferative and proliferative stages.

- **Non-proliferative diabetic retinopathy** is characterized by the presence of microaneurysms, intraretinal hemorrhages, or microvascular abnormalities (depending on the severity – Mild, Moderate, or Severe).
- **Proliferative diabetic retinopathy (PDR)** is the presence of neovascularization of the retina.

Both proliferative and non-proliferative diabetic retinopathy may be associated with Diabetic Macular Edema (DME) which produces retinal thickening. DME can be further subdivided into center-involving and non-center-involving by the location of the thickening relative to the center of the macula which is known as the fovea.

**Epidemiology**

Diabetic Retinopathy is the leading cause of legal and functional blindness for the working population (age 25-75). The overall incidence continues to increase along with the increased prevalence of diabetes. In Ontario, it is expected that almost all patients with Type I diabetes and more than 60% of patients with Type 2 diabetes will develop some form of diabetic retinopathy in the first 2 decades after the diagnosis of diabetes.

It is estimated that the prevalence of diabetes could increase to 1.9 million Ontarians by 2020. The overall age and sex-adjusted incidence rose from 5.2% in 1995 to 8.8% in 2005. Factors influencing this projected increase in prevalence include our aging population, an increased prevalence of obesity, an increase in immigration from high-risk populations, as well as growth in aboriginal populations who have a rate of diabetes which is up to 5 times higher than the average population.

**Risk Factors**

The incidence of diabetic retinopathy decreases with tight glycemic and blood pressure control.

**Diagnosis of Diabetic Retinopathy**

Diabetic Retinopathy is typically diagnosed by ophthalmologists and optometrists through regular eye exams. These eye exams should include:

- Visual acuity measurement
- Measurement of intraocular pressure (IOP)
- Evaluation for presence of iris neovascularization and lens opacities
- Dilated fundus examination with slit lamp biomicroscopy

Patients with non-proliferative retinopathy, showing progression of the disease, but without signs of macular edema, should have more frequent eye examinations. Any patients showing signs of macular edema or neovascularization of the retina should be referred directly to a treating Ophthalmologist.
The treating Ophthalmologist may conduct further specialized ophthalmologic testing, such as Ocular Coherence Tomography (OCT) or Intravenous Fluorescein Angiography (IVFA), depending on the clinical findings. An appropriate treatment approach will be determined based on the findings.¹

4.2 AGE-RELATED MACULAR DEGENERATION

Age-related Macular Degeneration (AMD) is a disease that causes loss of central vision due to damaged cells in the macula. Age-related macular degeneration makes it harder to do things that require sharp central vision, like reading, driving, and recognizing faces. It does not affect peripheral vision, so it does not lead to complete blindness.

There are two types of macular degeneration—wet and dry.

- The dry form is the most common type. It progresses more gradually with age. Waste deposits, called drusen, build up under the macula and with time central vision deteriorates.
- The wet form is less common, but it progresses more quickly and is more severe. This occurs when abnormal blood vessels grow into the retina from below through areas of damage. These blood vessels leak blood and fluid into the macula. This can quickly damage the macula, distorting and destroying central vision.²

Epidemiology

AMD affects nearly 1 million Canadians. The prevalence of the disease in Canada for all ethnic groups is 10.9%.³

Risk Factors

Everyone is at risk for developing AMD, however there are specific factors that increase the risk, some of which are uncontrollable.

Age, family history and ethnicity are the greatest uncontrollable risk factors to AMD. People over the age of 55, whose close relative(s) have been diagnosed with it and who are Caucasian are the most at risk for developing AMD. Furthermore, smoking, unhealthy diet and poor physical health, all increase the risk of developing AMD.³

Diagnosis of Macular Degeneration

AMD is diagnosed by an ophthalmologist or optometrist through a dilated fundus examination with slit lamp biomicroscopy.

Wet AMD is currently the only form of AMD that is directly treatable. Treatment is done through the administration of intraocular injections.

### 4.3 Retinal Tear and Detachment

With age, the vitreous tends to liquify slightly and take on a more watery consistency. Sometimes as the vitreous shrinks, it exerts enough force on the retina to produce a tear. Retinal tears can lead to a retinal detachment. Fluid vitreous, passing through the tear, lifts the retina off the back of the eye like wallpaper peeling off a wall.\(^4\)

A retinal detachment is a serious problem that usually causes blindness unless treated. The sudden appearance of flashing lights, floating objects, or a curtain moving across the field of vision are all possible indicators of a retinal detachment. Patients should be evaluated as soon as possible once symptoms are identified, and if a detachment is detected, urgent or emergent treatment is usually required.

**Risk Factors**

A retinal tear or detachment can occur at any age, but it is more common in people over age 40. It affects men more than women, and affects Caucasians more than other visible minorities.

A retinal detachment is also more likely to occur in people who:

- Are extremely nearsighted,
- Have had a retinal detachment in the other eye,
- Have a family history of retinal detachment,
- Have had cataract surgery,
- Have other eye diseases such as lattice degeneration, which alters the vitreoretinal interface.
- Have had an eye injury.\(^5\)

**Diagnosis of Retinal Tear or Detachment**

When a patient experiences signs and symptoms suggestive of a tear or detachment, they should be referred directly to an ophthalmologist or optometrist. The tear or detachment is diagnosed through slit lamp biomicroscopy and indirect ophthalmoscopy.

If a tear is detected, referral to a treating ophthalmologist should be made as soon as possible, preferably within 24 hours. If a detachment is detected, a consultation request to a treating ophthalmologist should occur immediately.

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4.4 Vitreomacular Traction, Macular Holes and Epi-retinal Membranes

With age, the vitreous undergoes progressive liquefaction and eventually separates from the retina. In some individuals the separation is incomplete which leads to traction on the macular retina which can cause visual distortion. Separation can occur spontaneously in about 30% of cases. However, if this does not occur, the retina may thin centrally producing a macular hole and further visual loss.

Alternatively, localized traction (VMT- vitreomacular traction syndrome) on the macula can cause distortion of the retinal contour resulting in symptoms of micropsia (objects appearing smaller), distortion or visual blurring. During or following the separation process cells may proliferate on the surface of the retina producing an epiretinal membrane. These membranes may contract with time and produce distortion in vision and visual loss.  

Epidemiology

The prevalence of symptomatic vitreomacular traction is difficult to determine, however some estimates suggest that 1% of the population may have symptoms at one point. The prevalence of macular holes has been found to be 0.3% of the general population and increases to 0.8% of the population over the age of 75. With the aging population it is anticipated that the incidence of macular holes will increase. Women are 3 times more likely to experience macular holes than men. Epiretinal membranes affect 11.8% of the population.

Risk Factors

Age is the primary risk factor for the development of epiretinal membranes, but additional risk factors include:

- History of a retinal tear or detachment
- Diabetes
- Retinal venous occlusions
- Inflammation in the eye (uveitis)
- Any intraocular surgery
- Laser or cryopexy surgery

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Risk factors for macular holes include age, myopia, trauma, or ocular inflammation. A person’s risk of a macular hole increases by 10-15% if a macular hole exists in their other eye.\(^\text{10}\)

**Diagnosis**

Patients with vitreomacular traction, macular holes and epiretinal membranes typically complain of blurring in their central vision or that their perception of straight lines is wavy. These diseases are typically detected by slit lamp biomicroscopy and confirmed by OCT testing.\(^\text{11}\)

### 4.5 Retinal Vein Occlusion

There are two types of Retinal Vein Occlusion: Branch Retinal Vein Occlusion (BRVO) and Central Retinal Vein Occlusion (CRVO).

BRVO, or relative blockage of a small retinal vein, can result in a painless decrease in central vision. This usually occurs when leakage of fluid from these blocked veins drains into the macular area producing macular swelling or cystoid macular edema (CME)). BRVO can also cause central visual loss if there is bleeding into the macula or if the blockage is severe enough to limit the blood supply to this area (ischemia). If there is significant loss of blood supply, then new blood vessels on the surface of the optic nerve (NVD) or elsewhere on the retina (NVE) can develop. These abnormal blood vessels can grow and potentially bleed into the vitreous cavity or cause traction on the retinal surface, leading to tractional retinal detachment.

CRVO, or relative blockage of the main vein which drains the retina, can similarly lead to central visual loss due to CME or macular hemorrhage or ischemia. In addition, if there is sufficient retinal ischemia, CRVO can lead to anterior segment neovascularization (neovascularization of the iris [NVI] or neovascularization of the angle [NVA]) which can lead to painful secondary neovascular glaucoma (NVG).

Both of these retinal vascular conditions can result in severe visual loss or blindness.

**Epidemiology**

Retinal Vein Occlusion typically occurs in patients over 60 years of age. BRVO is three times more common than CRVO.\(^\text{12}\)

**Risk Factors**

High blood pressure is the most common condition associated with *branch retinal vein occlusion* (BRVO).

About 10% to 12% of the people who have BRVO also have glaucoma (high pressure in the eye).

---


CRVO commonly occurs with glaucoma, diabetes, age-related vascular disease, high blood pressure, and blood disorders.\cite{12}

**Diagnosis**

Retinal Vein Occlusions are typically diagnosed by clinical examination with adjunctive testing such as OCT or IVFA.\cite{12}

### 4.6 POST-CATARACT ENDOPHTHALMITIS

Post-Cataract endophthalmitis is defined as severe inflammation involving both the anterior and posterior segment of the eye following cataract surgery. Infectious endophthalmitis is caused by the introduction of microbial organisms into the eye either from the patient's skin surface or from contaminated instruments. Most cases of postoperative endophthalmitis occur within 6 weeks of surgery.\cite{13}

**Risk Factors**

Risk factors for post-cataract endophthalmitis include:

- Sex (Males are more likely to develop endophthalmitis)
- Age (patients >85)
- Patient with capsular rupture are ten times more likely to develop endophthalmitis.\cite{14}

**Diagnosis**

Patients typically present with one or some of the following symptoms: decreased vision, pain (absent in 25% of patients), increased sensitivity to light or increased floaters. Clinical examination is required to diagnose endophthalmitis. Clinical signs of endophthalmitis include: lid edema, conjunctival chemosis/erythema, corneal edema, exaggerated anterior chamber inflammation, hypopyon (absent in 25% of patients), vitritis, and retinal periphlebitis.

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5. THE INTEGRATED RETINAL CLINICAL PATHWAY

The following section will outline the integrated clinical pathway for retinal patients which is broken down into subsections including Screening, Decision to Treat, Treatment (Vitrectomy/Scleral Buckle, Laser, and Intraocular Injection), and follow-up care.

This integrated pathway helps to delineate the key elements of retinal care which have been arrived at through a combination of clinical evidence and clinical consensus.

It is recognized that specific diseases require different aspects of the treatment pathway and may require several aspects of treatment at different times during the disease course; however for the sake of showing a continuum of care they are depicted as a linear progression.

5.1 SCREENING PATHWAY

Regardless of the diagnosis or the treatment option, all retina pathways start with the same screening process. Figure 6 outlines this screening process and highlights the clinical findings which warrant referral for further diagnosis and treatment. These clinical findings are highlighted in red.

Figure 6 – Retinal Screening Pathway

Retinal Screening Pathway for Diabetic Retinopathy, AMD, Vein Occlusion, Epiretinal Membrane, Macular Holes and Retinal tears/Detachments

| Education to Family Practitioners and the Public: |
| ✓ Risk factors for eye disease |
| ✓ Need for annual eye exams: |
|  • For all over 60* |
|  • For all patients with Type I diabetes beginning 5 years after diagnosis |
|  • For all patients with Type II diabetes beginning at diagnosis |
| ✓ Need to monitor central vision in each eye |
| ✓ Importance of early assessment for flashes and floaters (especially when associated with field loss) |

**Regulated Eye Exam by an Optometrist or Ophthalmologist:**
- Vision
- Intraocular Pressure
- Anterior segment and Lens exam
- Dilated Fundus exam with slitlamp biomicroscopy and/or indirect ophthalmoscopy
- Report to Family Practitioner/Endocrinologist/Internist if patient is diabetic

**Diabetic Retinopathy Identified:**

- Regular eye exam findings suggest Dry AMD.
  - Discuss home monitoring and AREDS study results (I and II)
- Mild/Moderate** Nonproliferative DR with good vision and no signs of macular edema – Return Visit in 6-12 months**
- Severe** Nonproliferative DR with good vision and no signs of macular edema
- Mild/Moderate/Severe Nonproliferative DR with signs of Macular Edema*
- Proliferative Diabetic Retinopathy

- Regular eye exam findings suggest Wet AMD
  - Striae, Macular Hole, Loss of Foveal Definition

- Regular eye exam shows changes consistent with Retinal Vein Occlusion with signs of edema or reduced vision.

**Ongoing monitoring and screening for new signs and symptoms:**

- Examination by optometrist/Non treating ophthalmologist reveals a retinal tear or detachment
* Routine eye examinations are NOT an insured service under age 65  
**Please see COS guidelines for clinical definitions of Mild, Moderate, Severe, non-proliferative and Proliferative DR and treatment protocols for Type1/Type II/pregnant patients.

Education
The pathway starts with education to the public and to general practitioners about the key risk factors of eye disease.

Annual Eye Exams: Although it is recommended that everyone have their eyes regularly examined, populations who are at greater risk for eye disease should be examined more frequently. It is recommended that all people over the age of 60 have an annual eye exam because the incidence of retinovascular disease and macular disease increases at this point.

It is important to note that OHIP only insures patients for an annual eye exam if they are younger than 20, once they have reached the age of 65, or if they have a medical condition which their primary care provider identifies as needing regular monitoring, such as diabetes.

According to the Canadian Ophthalmological Society (COS) guidelines for diabetic retinopathy, all patients with Type I diabetes should receive an annual eye exam starting 5 years after they are first diagnosed with diabetes. All patients with Type II diabetes should receive an annual eye exam starting as soon as they are diagnosed. Once eye disease is identified more frequent examination is required.

Patients with Type I or Type II diabetes who are considering pregnancy should be counselled to undergo an eye examination by an ophthalmologist or optometrist before attempting to conceive. Repeat assessments should be carried out during the first trimester of pregnancy and as indicated by the stage of retinopathy and the rate of progression during the remainder of the pregnancy and through the first year post-partum.¹⁵

When to seek emergency care: Patients should also be educated about when to seek emergency treatment as well as how best to access care.

If at all possible, persons presenting with the acute onset of symptoms suggestive of a retinal tear or detachment should be referred directly to an ophthalmologist or optometrist rather than sending them to an Emergency department where the specialized equipment and skills that are necessary to make this diagnosis are not usually present.

The Eye Exam
The eye exam should consist of the following key examination elements:
- Visual Acuity
- Intraocular pressure
- Anterior Segment and Lens Exam
- Dilated Fundus exam with slit-lamp biomicroscopy and indirect ophthalmoscopy

At the completion of the visit, a report should be created and sent to the family practitioner (referring physician or patient-identified primary health care provider) regarding the examination findings and the suggested interval for re-examination. The patient’s endocrinologist or internist should also be copied if the patient has diabetes.

Depending on the findings of the eye exam a patient may have to be referred for further assessment and treatment. If their symptoms have not progressed to the point of requiring treatment they may instead receive ongoing monitoring and screening to monitor disease progression.

The following findings (highlighted in red in the diagram above) necessitate referral for further assessment and possible treatment:

- Mild/Moderate/Severe Non-proliferative Diabetic Retinopathy with signs of Macular Edema
- Severe Non-proliferative Diabetic Retinopathy.
- Proliferative Diabetic Retinopathy
- Wet Age-related Macular Degeneration
- Suspicious Macular Findings with symptomatic visual reduction (Striae, Macular Hole, Loss of Foveal Definition)
- Retinal Vein Occlusion with signs of edema, visual reduction or retinal or iris neovascularization.

5.2 Decision to Treat Pathway

Once referred, all retina patient groups are examined and diagnosed by a treating ophthalmologist. At this point, this individual will conduct a further eye examination which may include specialized testing to achieve a more accurate diagnosis. This specialized testing may include Ocular Coherence Tomography (OCT), Intravenous Fluorescein Angiography (IVFA), visual electrophysiologic tests, or ocular ultrasonography or visual field testing.

From here it is determined whether a patient will follow a medical pathway and receive intraocular injection therapy (Anti-VEGF therapy); whether they will receive laser therapy which is usually, but not always, provided within a hospital, surgery center or IHF, or if they will be on the surgical pathway and receive surgical treatment at a hospital, surgery centre, or IHF.

This decision is based on a complex algorithm of criteria which is not solely dependent on the diagnosis. For example, a patient with centre involving diabetic macular edema may be eligible for intraocular injections, laser therapy, or vitrectomy (surgery) depending on the result of their clinical examination specialized testing and response to previous therapy. On the other hand, a patient with wet age-related macular degeneration most often has only one treatment pathway; intraocular injection, although several different drugs could potentially be used. These decision criteria will be outlined in subsequent sections of the handbook.
Intraocular injections are also performed in hospital/IHF. Laser therapy is most commonly performed in an ambulatory setting in a hospital, ambulatory clinic, or IHF, largely due to the high cost of operating and maintaining a laser. Laser is also an integral part of the operative surgery for diabetics and for patients with retinal detachments. Rarely, however laser treatment may be performed in ophthalmology clinic or office.

5.3 SURGICAL RETINA PATHWAYS

5.3.1 VITRECTOMY AND SCLERAL BUCKLE
The pathway below outlines the pre-treatment and follow-up protocols for vitrectomy and scleral buckle surgeries. These were developed through clinical consensus with the support of clinical evidence. These protocols are consistent for all patients regardless of the surgical procedure used. The specific surgical procedure used will vary depending on patient characteristics, pathology, and surgeon preference.

The procedure will often entail the use of a pharmacological adjunct and/or adjunctive device to achieve the desired results. For example, a vitrectomy may require the use of an endolaser to coagulate tissue, or the use of silicone oil or gas to keep the retina attached postoperatively. These adjuncts are used at the discretion of the surgeon based on the needs of the patient. Some of these adjuncts (silicone oil; perflurocarbon liquids, and endolaser) are costly and have the potential to significantly drive up the case cost, particularly if several are required simultaneously e.g. proliferative retinopathy, complex retinal detachments.
Vitrectomy and/or Scleral Buckle

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Follow-up</th>
</tr>
</thead>
</table>
| • Identification of operated eye  
• Surgical Pause  
• Anesthesia (as appropriate)  
• Povidone Prep  
• Draping (as appropriate) | Follow up visit typically within 36 hrs of procedure**:  
• Visual Acuity  
• IOP  
• Lens Status  
• Dilated Fundus Exam  
• Level of inflammation/hemorrhage  
• Retinal Status | Regular observation by treating surgeon or delegate** with final assessment when patient becomes stable enough to leave follow up to referring practitioner | Periodic communication to FP, referring physician/optometrist and summary note at completion of specialist follow-up |
| Procedure* | | Monitor until stable then discharge.  
• Instruction regarding potential complications and symptoms/signs along with emergency contact info and follow up time and place should be provided verbally and in writing.  
• An operative report should be prepared. | |

*Procedures used vary depending on patient characteristics and pathology. Surgery often entails the use of adjunctive drugs and devices.  
**Usually carried out by the treating surgeon but may be delegated to an individual with demonstrated competence to detect complications if returning to treating surgeon is not feasible.

**Follow-up:** It is recommended that post-surgical follow-up occur within 36 hours of the procedure by the treating surgeon. However, there are instances where it is not feasible for the patient to return to the treating surgeon within that time frame (e.g. they have travelled from Northern Ontario for treatment). In these cases it may be appropriate for post-surgical follow up to be carried out by a delegate with demonstrated competence to detect post-surgical complications.

Similarly, it is recommended that regular observation and final assessment be carried out by the treating surgeon until the patient is stable enough to return to their referring physician. Again, in instances where travel to the treating surgeon is not feasible, a delegate with demonstrated competence to detect complications can carry out regular observation.

**Communication:** The treating surgeon should be in periodic communication with the patient’s family physician and referring physician/optometrist. An operative report should be prepared and shared with the providers on the care management team as well as a summary note at completion of treatment.

5.3.2 LASER
Laser therapy may be used in the treatment of diabetic retinopathy, vein occlusion and retinal tears/detachments. The pre-treatment protocols are the same for all laser treatments however, as depicted in the pathway below, follow-up varies depending on the diagnosis.

**Figure 9 – Clinical Pathway for Laser Treatment**

<table>
<thead>
<tr>
<th>Laser</th>
<th>Anesthesia*</th>
<th>Ensure adequate pupil dilation</th>
<th>Safety glasses for observers</th>
<th>Follow approved procedures for cataract lens disinfection</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Instruction regarding potential complications and symptoms/signs.</td>
<td>Emergency Contact Info</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>If Retinopathy/ Vein Occlusion</th>
<th>Reassess at appropriate intervals to verify regression of neovascularization or retinal thickening.***</th>
<th>If still present, retreat or use alternative treatment method.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Follow-up</td>
<td>If regression, regular observation by treating ophthalmologist until stable.</td>
<td>Regular observation by treating ophthalmologist**** until stable. Communication to family physician, referring ophthalmologist/ optometrist at completion of treatment, at time of discharge from care and if there is a significant change in status.</td>
</tr>
<tr>
<td>If Retinal Tear</td>
<td>Final Assessment to determine success†</td>
<td>Return to referring ophthalmologist/optometrist for ongoing follow up. Letter to referring physician/OD/FP outlining patients’ status at completion of follow up.</td>
</tr>
<tr>
<td></td>
<td>• IOP</td>
<td>• Dilated Fundus Exam with scleral depression or wide angle for contact lens exam</td>
</tr>
</tbody>
</table>

* A crash cart must be present if peribulbar or retrobulbar anesthesia is being used.
** Treatment algorithms continue to evolve; treatment should follow current guidelines and community standards.
*** In most cases clear evidence of treatment effect may not be observed for 3 months or longer.
**** This is usually done by the treating ophthalmologist but may be delegated to an individual with demonstrated competence to detect problems if returning to treating surgeon is not feasible.
† This may be done by the treating Ophthalmologist or delegated to the referring Ophthalmologist/Optometrist and is usually carried out 4-6 weeks post treatment.

**Follow-up:** In patients with diabetic retinopathy or vein occlusion follow up visits are used to monitor regression of neovascularization and/or retinal thickening. If there is no regression, the patient might require retreatment or an alternative treatment method. This follow-up is performed by the treating the ophthalmologist until regression is achieved. It is recommended that regular observation and final assessment be carried out by the treating surgeon until the patient is stable enough to return to their referring physician. However, in instances where travel to the treating surgeon is not feasible, a delegate with demonstrated competence to detect complications can carry out regular observation.
In patients with retinal tears, the follow-up is similar to surgical follow-up. It is recommended follow-up occur within 4-6 weeks of the procedure by the treating surgeon. However, in cases where travel to treating ophthalmologist is not possible it may be appropriate for follow up to be carried out by a delegate with demonstrated competence to detect post-surgical complications.

Additional Notes: Laser treatment is not always performed in a hospital or surgery centre setting. When laser is performed in a clinic or office patient safety protocols should be in place. The clinic should have protocols for dealing with medical complications. The clinic should also be equipped with a crash cart with at least a ventilation mask if peribulbar or retrobulbar blocks are being used.

5.4 INTRAOCULAR INJECTION PATHWAY

Intraocular injections are used most commonly to treat specific types of Diabetic Macular Edema, macular edema secondary to retinal vein occlusions, as well as to treat Wet Age-related Macular Degeneration. They can also be useful in a number of other circumstances. There are specific inclusion criteria and treatment protocols for each diagnosis. Those for the common indications will be outlined in more detail in the subsequent section of this report. However, the protocols for pretreatment and follow-up care are consistent for most intraocular injection patients.

Figure 10 – Clinical Pathway for Intraocular Injections

Intraocular Injections

*Paracentesis is not generally required after injection except in some patients with glaucoma with optic nerves at risk. If paracentesis is performed, a clear explanation for why this additional procedure was done should be documented on each occasion.

**Most patients show response after three injections however some, particularly those with DME, require 6 injections.
6. Diagnosis-Specific Treatment Criteria

6.1 Diabetic Retinopathy

The decision to treat the various forms of Diabetic Retinopathy requires navigating a complex decision matrix and leads to great variability in the treatment protocols. Below are the inclusion criteria and treatment algorithms for Centre-involving Diabetic Macular Edema and Proliferative Diabetic Retinopathy. Each of the diagnosis may lead to vitrectomy, laser treatment, intraocular injection or any number of combinations of each, depending on the needs of the patient.

For patients presenting with macular edema a key consideration is the visual acuity and whether the edema involves the center of the macula. If the edema does not involve the macular center the best available evidence suggests that laser is the preferred treatment. For edema involving the centre of the macula but with good vision, observation or focal/grid laser may be the best approach.

Once vision has been affected there is level one evidence that treatment with intraocular VEGF inhibitors provides a superior visual outcome to laser treatment alone. A lower level of evidence suggests that, in pseudophakic patients, (those who have had cataract surgery), intraocular steroid may achieve comparable results, albeit with the additional risk of elevated intraocular pressure.

Level 1 evidence supports the use of panretinal laser in the management of proliferative retinopathy with “high risk” characteristics and/or neovascularization of the iris. In these patients intraocular injection of a VEGF inhibitor plays a critical role in initial management. There is good rationale and mounting evidence that the use of intraocular VEGF inhibitor injections reduces the short term risk of vision decrease following Pan-retinal Photocoagulation (PRP) in patients with diabetic macular edema and proliferative retinopathy. Similarly, for diabetic patients with NVI/A or NVG, particularly those who present with very high intraocular pressures, intraocular VEGF inhibitor injections may play an important role in the initial management and until such time that definitive and adequate panretinal laser photocoagulation can be applied.

When there is non-reabsorbing vitreous blood which precludes the placement of sufficient laser, a vitrectomy may be indicated, and where there is a retinal detachment from diabetic fibrovascular membranes that threaten or involve the fovea, a vitrectomy combined with laser is likely the treatment of choice. In the latter indication there is good evidence that pretreatment with a VEGF inhibitor a few days prior to vitrectomy may reduce bleeding, shorten surgical time, reduce the risk of rebleeding and improve outcomes.

At least one large Randomized Control Trial (RCT) has demonstrated that vitrectomy may significantly improve vision in patients with diabetic macular edema occurring in conjunction with vitreomacular traction.16

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**Figure 11 – Treatment Inclusion Criteria and Decision Algorithm for Centre-Involving Diabetic Macular Edema (DME)**

**Centre – involving Diabetic Macular Edema (DME)**

<table>
<thead>
<tr>
<th>Inclusion Criteria</th>
<th>Treatment Algorithm</th>
</tr>
</thead>
<tbody>
<tr>
<td>OCT confirms macular thickening with or without associated cystoid macular edema</td>
<td><strong>VA &gt; 20/30</strong></td>
</tr>
<tr>
<td></td>
<td>PHAKIC/PSEUDOPHAKIC</td>
</tr>
<tr>
<td></td>
<td>Consider fluorescein guided focal/modified grid laser photocoagulation</td>
</tr>
<tr>
<td></td>
<td>Consider intravitreal anti-VEGF therapy if symptoms attributable to edema present (A minimum of 4-6 monthly injections should be given before alternative considered)</td>
</tr>
<tr>
<td></td>
<td><strong>VA ≤ 20/30</strong></td>
</tr>
<tr>
<td></td>
<td>PHAKIC</td>
</tr>
<tr>
<td></td>
<td>Recommend Intravitreal anti-VEGF therapy (A minimum of 4-6 monthly injections should be given before alternative considered)</td>
</tr>
<tr>
<td></td>
<td>PSEUDOPHAKIC</td>
</tr>
<tr>
<td></td>
<td>Consider Intravitreal depot corticosteroid preparation combined with focal/modified grid laser photocoagulation</td>
</tr>
</tbody>
</table>

*Type of anesthesia varies depending on patient characteristics.*

**Figure 12 – Treatment Inclusion Criteria and Treatment Protocols for Pan-retinal Photocoagulation for Proliferative Diabetic Retinopathy**

**Pan- Retinal Photocoagulation (PRP) for Proliferative Diabetic Retinopathy**

<table>
<thead>
<tr>
<th>Inclusion Criteria</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Presence of anterior segment neovascularization (IF NVG present, consider concurrent anti-VEGF therapy)</strong> or</td>
<td><strong>Provide sufficient anesthesia</strong>*</td>
</tr>
<tr>
<td><strong>Presence of High Risk Characteristics (NVD&gt;½-¼ disk area, any NVD with VH, NVE with associated VH)</strong> or</td>
<td><strong>Ensure adequate pupil dilation</strong></td>
</tr>
<tr>
<td><strong>May consider for patients before HRC present if patient follow-up difficult or uncertain</strong></td>
<td><strong>Follow approved procedures for contact lens disinfection</strong></td>
</tr>
<tr>
<td><strong>If concurrent CSME present, pre-treat CSME with focal laser or anti-VEGF therapy</strong></td>
<td><strong>PRP Laser therapy administered with indirect ophthalmoscopy or contact lens.</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Number of sessions dependent on patient tolerance and clinical situation; normally divided into 2-4 sessions</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Informed consent for treatment (patient aware of risks of reduced night vision, reduced peripheral vision, loss of visual field, visual loss due to worsening macular edema)</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Written and verbal instructions regarding potential complications (including early and delayed VH), symptoms/signs and contact info</strong></td>
</tr>
</tbody>
</table>
6.2 RECOMMENDED APPROACH FOR INTRAOCULAR INJECTION OF VEGF INHIBITORS FOR WET AMD, DME AND RVO

At this point in time evidence supports the use of intraocular injection of VEGF Inhibitor agents (Lucentis® [Ranibizumab], Avastin® [Bevacizumab], Eylea® [Aflibercept]) to treat:

- Macular edema caused by branch and central retinal vein occlusions (BRVO/CRVO),
- Diabetic Macular Edema (DME), and
- Wet Age-Related Macular Degeneration (wAMD).

These drugs have other indications as well, which are supported by varying levels of evidence. They can also be used as a surgical adjuvant.

There is evidence that intraocular steroid (Triamcinolone; Ozurdex®) is effective in treatment of macular edema associated with retinal vein occlusions and DME. The side effect profile of this class of drugs limits their use to the second line of intervention in most circumstances.

A brief summary of the evidence supporting the use of the agents is found in Table 1.
TABLE 1: Summary of VEGF Inhibitor Injection Agents

<table>
<thead>
<tr>
<th></th>
<th>EFFICACY</th>
<th>ADVANTAGES</th>
<th>DISADVANTAGES</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Lucentis® (Ranibizumab):</strong></td>
<td>Superior to laser or steroid in the management of DME in phakic eyes</td>
<td>Best evidence to date of effectiveness, few side effects, little loss of effectiveness over time, increased number of binding sites/size versus bevacizumab</td>
<td></td>
</tr>
<tr>
<td><em>Humanized monoclonal antibody FAB fragments which bind all isoforms of VEGF.</em></td>
<td>Prevents progression of visual loss in 90% of patients in pivotal trials in wAMD and improves vision in 30% when used monthly. Reduces the vision loss in branch and central vein occlusion</td>
<td>•<strong>Superior to laser or steroid in the management of DME in phakic eyes</strong> •**Prevents progression of visual loss in 90% of patients in pivotal trials in wAMD and improves vision in 30% when used monthly. •<strong>Reduces the vision loss in branch and central vein occlusion</strong> •<strong>Best evidence to date of effectiveness,</strong> •<strong>few side effects,</strong> •<strong>little loss of effectiveness over time,</strong> •<strong>increased number of binding sites/size versus bevacizumab</strong></td>
<td>•<strong>Cost versus bevacizumab or triamcinolone,</strong></td>
</tr>
<tr>
<td><strong>Avastin® (Bevacizumab):</strong></td>
<td>Shown to be effective in treatment of DME; RVO</td>
<td>Lower cost treatment compared to Ozurdex, Ranibizumab or Aflibercept</td>
<td>Proper compounding critical to safety and effectiveness Possible increase in systemic side effects.</td>
</tr>
<tr>
<td><em>Full-length humanized monoclonal VEGF inhibitor antibody (parent molecule for Ranibizumab)</em></td>
<td>As effective as Ranibizumab for wAMD when dosed monthly but less effective if using PRN protocol.</td>
<td>•<strong>As effective as Ranibizumab for wAMD when dosed monthly but less effective if using PRN protocol.</strong></td>
<td>•<strong>Lower cost treatment compared to Ozurdex, Ranibizumab or Aflibercept</strong></td>
</tr>
<tr>
<td><strong>Eylea® (Aflibercept):</strong></td>
<td>Effective in treatment of macular edema in RVO and DME</td>
<td>Possibly less frequent dosing (wAMD), Possibly fewer monitoring visits, different mechanism of action</td>
<td>Cost implications unclear</td>
</tr>
<tr>
<td><em>Recombinant fusion protein containing VEGF binding receptors which bind all isoforms of VEGF and placental growth factor.</em>*</td>
<td>Equally effective as Ranibizumab in treatment of wAMD when dosed every two months following 3 monthly loading doses in pivotal trials</td>
<td>•<strong>Equally effective as Ranibizumab in treatment of wAMD when dosed every two months following 3 monthly loading doses in pivotal trials</strong></td>
<td>•<strong>Cost implications unclear</strong></td>
</tr>
</tbody>
</table>

A new pharmacologic agent, Ocriplasmin (Jetrea), has recently been approved by Health Canada for intraocular injection of symptomatic VMA (vitreomacular adhesion). It can also be used to treat some vitreomacular traction syndrome and macular hole cases. The role that it will play in the management of these diseases remains to be determined.

Across Canada, the various provinces have introduced these drugs in a variety of ways. There is no consistency as to which drugs are covered or for which indications they are covered for. In Ontario, the ODB currently only covers the cost of Lucentis® for patients that qualify for the ODB program. The drug is covered for wet AMD, DME, and RVO.

Table 2 below outlines the coverage and indications for each of the provinces and territories of Canada.
TABLE 2: Provincial Comparison of VEGF Inhibitor Agent Coverage by Indication

<table>
<thead>
<tr>
<th>PROVINCE/TERRITORY</th>
<th><strong>LUCENTIS</strong></th>
<th><strong>AVASTIN</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>British Columbia</td>
<td>wet AMD</td>
<td>wet AMD</td>
</tr>
<tr>
<td>Alberta</td>
<td>wet AMD; diabetic macular edema</td>
<td>No coverage</td>
</tr>
<tr>
<td>Saskatchewan</td>
<td>wet AMD, diabetic macular edema, retinal vein occlusion</td>
<td>No coverage</td>
</tr>
<tr>
<td>Manitoba</td>
<td>wet AMD</td>
<td>wet AMD</td>
</tr>
<tr>
<td>Ontario</td>
<td>wet AMD, diabetic macular edema, retinal vein occlusion</td>
<td>No Coverage</td>
</tr>
<tr>
<td>Quebec</td>
<td>wet AMD, diabetic macular edema, retinal vein occlusion</td>
<td>No Coverage</td>
</tr>
<tr>
<td>New Brunswick</td>
<td>for wet AMD, diabetic macular edema</td>
<td>wet AMD</td>
</tr>
<tr>
<td>Nova Scotia</td>
<td>wet AMD</td>
<td>wet AMD</td>
</tr>
<tr>
<td>Prince Edward Island</td>
<td>wet AMD</td>
<td>No Coverage</td>
</tr>
<tr>
<td>Newfoundland and Labrador</td>
<td>Covered according to special eligibility criteria established by the Newfoundland and Labrador Prescription Drug Program's Special Authorization provision.</td>
<td>No Coverage</td>
</tr>
<tr>
<td>Yukon</td>
<td>wet AMD, diabetic macular edema, retinal vein occlusion</td>
<td>wet AMD, diabetic macular edema, retinal vein occlusion</td>
</tr>
<tr>
<td>Northwest Territories</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Nunavut</td>
<td>NA</td>
<td>NA</td>
</tr>
</tbody>
</table>

Although most patients appear to receive appropriate therapy in the initial year of treatment, a disturbingly high percentage of patients appear to discontinue treatment after one and two years of therapy which suggests that patients may not be achieving the best long-term benefits of these drugs which can only be achieved by ongoing monitoring and therapy.

The burden of follow-up and testing required to monitor treatment for both patients and practitioners is significant, with access issues a problem in the rural and remote areas of the province.

It is recommended that the Ministry review its ODB policies around access to VEGF Inhibitor Injection agents including Avastin® and Eylea®. These drugs should be evaluated on the basis of their efficacy, safety and ability to improve patients’ access to a range of treatment options, but should also consider the advantages and limitations of each.

- Greater use of Avastin® (Bevacizumab) may have the potential to reduce the cost burden of the treatment of these diseases to the taxpayers; however the importance of proper compounding of this drug into individual doses needs to be considered to ensure public safety. A higher incidence of systemic side effects may also exist with this drug. The significance of these remains to be determined.
The introduction of Eylea® (Aflibercept) into the formulary may reduce the frequency of patient visits, testing and possibly injection frequency which may ease access problems. The relative cost of this drug in clinical practice remains to be determined.

**RECOMMENDATION:**

It is recommended that the Ministry review its ODB policies around access to VEGF Inhibitor Injection agents including Avastin® and Eylea®.

### 6.2.1 Wet Age-Related Macular Degeneration

Patients with Wet AMD have been shown in multiple RCTs to benefit visually from treatment with intraocular injections of VEGF inhibitors. Approximately 90% of treated patients stabilize vision and 30% of patients will show significant visual improvement. Untreated patients usually go on to lose vision which limits their independence and quality of life.

As patients with disease in one eye have greater than a 50% risk of developing the disease in their other eye within 2-5 years, preservation of vision in the first eye is important as it is not possible to predict which eye will ultimately retain better vision.

Regular follow up and specialized diagnostic testing (OCT and sometimes IVFA) are required on an ongoing basis in order to detect recurrence. Data from several well conducted studies shows that when vision worsens during treatment due to an undetected recurrence it is unlikely to return to the previous level despite reintroduction of therapy. Recurrences occur throughout the patient’s lifetime and have the potential to cause vision loss.

Because of this ongoing need for close monitoring and treatment, treatment of this disease poses considerable burden on patients and their families as well as the health care system. It is important that patients who have the most potential to benefit are treated rapidly, yet it is also important to modify or discontinue treatment if it is not producing the expected response.

**Recommended Approach for Intraocular Injection of VEGF Inhibitors for Wet-AMD**

The practices outlined below are recommended as the best way to ensure wet-AMD patients receive the best care. These recommendations encourage re-evaluation of treatment which is failing to achieve the desired end point so as to reduce the burden of potentially unnecessary or inappropriate treatment on patients, their families and the health care system.

**Guidelines for initiating therapy:**

For patients undergoing treatment of wet-AMD it is suggested that the following considerations apply:

- To receive treatment for wet AMD patients should be documented to meet the following criteria:
  - Age >50;
  - Recent onset of decreased vision or distortion;
  - Presence of drusen;
  - Presence of subretinal haemorrhage associated with retinal thickening; and/or
OCT evidence of intraretinal fluid and/or subretinal fluid (but not solely pigment epithelial detachment [PED]) along with subretinal changes consistent with wet-AMD

- Absence of other pathology to explain visual change
- Absence of medical or ocular contraindications to intraocular injection
- Absence of ocular or systemic pathology which would negate the possibility of vision benefit with treatment.
- Patient agrees to return for regular follow-up at intervals as frequently as monthly; potentially for life if treatment is successful.

In some cases, patients may not meet the criteria listed above for wet-AMD treatment, but may still possibly benefit from treatment. Obtaining an OCT and often an IVFA is necessary to confirm the diagnosis in this circumstance. Once a firm diagnosis of wet AMD is established, the conduct of therapy will otherwise continue as below.

**Conduct of therapy:**

- Treatment will normally be initiated with a series of three monthly injections of a VEGF inhibitor with a formal evaluation of treatment effect occurring at the 3rd or 4th month.
  - To continue in this treatment pathway patients should demonstrate significant reduction (or absence) of intraretinal fluid or significant reduction (or absence) of subretinal fluid, haemorrhage, or retinal thickening. Patients who do not demonstrate these changes should be carefully assessed to determine the reason (incorrect diagnosis, inactive disease with findings mimicking activity, disease unresponsive to treating agent).
  - If none of these apply, a review by a retinal subspecialist (or a colleague experienced in the management of wet AMD if access to a retinal specialist is limited by geography) should occur and a mutually agreed upon treatment plan established
  - Where geography limits access to specialist care this review may also be conducted through teleophthalmology if available.
- Beyond this point continued follow-up and treatment should continue with intervals not usually greater than 3 months; with vision, intraocular pressure, and a fundus examination documented for each visit.
- In the absence of visible subretinal blood and retinal thickening, an OCT should be obtained at each visit to document the ongoing effectiveness of, and need for, therapy. Increase in intraretinal or subretinal fluid or development of new haemorrhage should prompt a re-evaluation of treatment and frequency.

**Guidelines for discontinuation of therapy:**

- Loss of useful vision secondary to irreversible structural change
- Development of ocular or systemic disease precluding intraocular injection
- Inability to maintain regular follow-up
- Patient desire to discontinue treatment
THE OHTAC REVIEW - OCT IN MONITORING THE TREATMENT OF WET AMD

The Ontario Health Technology Assessment Committee (OHTAC) conducted an evidence-based review of Optical Coherence Tomography (OCT) in monitoring the treatment of wet AMD. OHTAC findings suggest that during active intraocular injection therapy for macular disease, access to OCT should be provided monthly as the basis for treatment. In any given patient, access should be available monthly as this is required during initial treatment until the patient is stable, evidence (retrospective and one small prospective study) suggests that not all patients need to be followed monthly once stable to maintain good visual results.

In Ontario, a “treat and extend” protocol is the dominant method of wet AMD care because clinical evidence suggests it works well for most patients and provides a lesser follow up burden on patients and practitioners than monthly treatment. Although this method of care requires fewer than monthly OCT tests, access to monthly OCT testing needs to be maintained for when a patient experiences a recurrence of the disease and must increase their treatment to a monthly protocol. Further evidence determining the effectiveness of the “treat and extend” method is anticipated to be published in the future.

Current data indicates that approximately 80% of patients in North America are managed using a PRN or “treat and extend approach”. In Ontario this has reduced the average number of injections provided to an average of one injection every 2 months (Source: ODB data).

6.2.2 DIABETIC MACULAR EDEMA (DME)

Patients with DME have been shown in multiple RCTs to benefit visually from treatment with intraocular injections of VEGF inhibitors. Use of these agents produces a greater improvement in vision than focal laser, and may reduce disease progression. Some evidence also demonstrates improvement of DME following injection of intraocular steroid albeit with an increased risk of cataract formation in phakic individuals and intraocular pressure rise in both phakic and pseudophakic individuals.

This disease responds less rapidly to treatment than does AMD so several injections may be required to see peak effect, however need for injections does appear to decrease over time.

Because of this ongoing need for close monitoring and treatment, treatment of this disease poses considerable burden on patients and their families as well as the health care system. It is important that patients who have the most potential to benefit are treated rapidly, yet it is also important to modify or discontinue treatment if it is not producing the expected response.

The practices outlined below are recommended as the best way to ensure DME patients receive the best care. These recommendations encourage re-evaluation of treatment which is failing to achieve the desired end point so as to reduce the burden of potentially unnecessary or inappropriate treatment on patients, their families and the health care system.

Guidelines for initiation of therapy:
For patients undergoing treatment for DME it is suggested that the following considerations apply:

- To receive treatment for DME patients should be documented to meet the following criteria:
  - Presence of mild moderate or severe diabetic retinopathy
- Vision less than 20/25 (6/7.5) or symptoms attributable to DME
- Presence of center involving DME (documented by OCT or contact lens biomicroscopy)

- Absence of medical or ocular contraindications to intraocular injection
- Absence of ocular or systemic pathology which would negate the possibility of vision benefit with treatment.
- Patient agrees to return for regular follow-up at intervals as frequently as monthly; potentially for life if treatment is successful.

**Conduct of therapy:**
- Treatment will normally be initiated with a series of three monthly injections of a VEGF inhibitor with a formal evaluation of treatment effect occurring at the 3rd or 4th month.
  - Patients should demonstrate some reduction of DME at this time. In the absence of response injections may continue monthly up to a maximum of 6 injections.
  - Patients who do not demonstrate a reduction in DME after 6 injections should be carefully assessed to determine the reason (incorrect diagnosis, disease unresponsive to treating agent). If, after this review, it is deemed that treatment should continue, a review by a retinal subspecialist (or a colleague experienced in the management of DME if access to a retinal specialist is limited by geography) should occur and a mutually agreed upon treatment plan established
    - Where geography limits access to specialist care this review may also be conducted through teleophthalmology if available.
  - Beyond this point continued follow-up and treatment should continue with vision, intraocular pressure, and a fundus examination documented for each visit.
  - An OCT should be obtained at each visit to document the ongoing effectiveness of therapy. Increase in intraretinal fluid or vision loss should prompt a re-evaluation of treatment and frequency.

**Guidelines for discontinuation of therapy:**
- Loss of useful vision secondary to irreversible structural change
- Development of ocular or systemic disease precluding intraocular injection
- Inability to maintain regular follow-up
- Patient desire to discontinue treatment

### 6.2.3 Retinal Vein Occlusion (RVO)

Patients with RVO (both BRVO and CRVO) have been shown in RCTs to benefit visually from treatment with intraocular injections of VEGF inhibitors. Evidence also demonstrates improvement of RVO following injection of intraocular steroid albeit with an increased risk of intraocular pressure rise (in phakic and pseudophakic patients) and cataract formation in phakic individuals.

This disease can respond rapidly to treatment and dramatic response can be seen after a single injection. The duration of treatment may sometimes be shorter than in DME and AMD as the perfusion improves over time although it may take a substantial amount of time for this to occur.

The practices outlined below are recommended as the best way to ensure RVO patients receive the best care. These recommendations encourage re-evaluation of treatment which is failing to achieve the desired
end point so as to reduce the burden of potentially unnecessary or inappropriate treatment on patients, their families and the health care system.

**Guidelines for the initiation of therapy:**
For patients undergoing treatment RVO it is suggested that the following considerations apply:

- To receive treatment for RVO patients should be documented to meet the following criteria:
  - Presence of RVO documented by clinical findings (and IVFA in equivocal cases)
  - Vision less than 20/25 (6/7.5)
  - Presence of macular edema (documented by OCT or contact lens biomicroscopy)
- Absence of medical or ocular contraindications to intraocular injection
- Absence of ocular or systemic pathology which would negate the possibility of vision benefit with treatment.
- Patient agrees to return for regular follow-up.

**Conduct of therapy:**
- Treatment may be initiated with a series of six monthly injections of a VEGF inhibitor before a formal evaluation of treatment effect occurs at the 6th month.
  - Patients should demonstrate significant reduction or absence of macular edema at this time. This normally should be associated with improved vision.
  - Patients who do not demonstrate a reduction in macular edema after 6 injections should be carefully assessed to determine the reason (incorrect diagnosis, disease unresponsive to treating agent). If, after this review, it is deemed that treatment should continue a review by a retinal subspecialist (or a colleague experienced in the management of RVO if access to a retinal specialist is limited by geography) should occur and a mutually agreed upon treatment plan established
    - Where geography limits access to specialist care this review may also be conducted through teleophthalmology if available.
- Beyond this point continued follow-up and treatment should continue regularly with vision, intraocular pressure, and a fundus examination documented for each visit.
- An OCT should be obtained at each visit to document the ongoing effectiveness of therapy. Increase in intraretinal or subretinal fluid should prompt a re-evaluation of treatment and frequency.

**Guidelines for discontinuation of therapy:**
- Stabilization of disease so treatment no longer required.
- Loss of useful vision secondary to irreversible structural change
- Development of ocular or systemic disease precluding intraocular injection
- Inability to maintain regular follow-up
- Patient desire to discontinue treatment

After stopping treatment, patients with CRVO need to be followed regularly for at least an additional year to assess for iris neovascularization.
6.3 **Retinal Tear or Detachment**

The window of opportunity for the most appropriate management of retinal tears and detachments is narrow and as a result access to care is required 24/7. This care may involve procedures generally, but not exclusively, done in an ambulatory care area of a hospital or IHF (laser or cryo with or without the injection of intraocular gas) or may involve more invasive surgery (vitrectomy or scleral buckle) in an operating room. Even for the same procedure, the complexity of the surgery varies widely with some patients requiring the use of one or more surgical adjuvants such as silicone oil, intraocular laser, chandelier lights, etc. Furthermore, the need for subsequent surgery is expected in 10-15% of cases.

Patients who present with new onset flashing lights or floaters in their vision need to be assessed quickly to determine if there is a retinal tear present. New onset retinal tears have a high risk of progressing to retinal detachment and this risk can be lowered significantly by laser or cryopexy. Patients with a new onset of a retinal detachment need to be assessed as soon as possible to determine how the detachment should be treated to preserve central vision and restore peripheral field.

Treatment of a detached retina may be accomplished in an office or clinic setting with injection of intraocular gas and laser or cryopexy, but commonly requires intervention in an operating room. This may require surgery after hours or on a weekend or in some cases may be done semi-electively depending on clinical circumstances and operating room access. A wide range of techniques may be required to reattach a detached retina, making these some of the most complex and unpredictable cases in retinal surgery.

Figure 14, below, outlines the pathways that a patient may follow.
FIGURE 14 - Treatment Inclusion Criteria and Decision Algorithm for Retinal Tear and Detachment

**Signs and symptoms Suggestive of Retinal Tear or Detachment**
- Education to FP and public about importance of early assessment for flashes/flosters especially when associated with field loss

**Initial Assessment**
- Signs and symptoms suggestive of tear or detachment should be referred directly to a practitioner that can diagnose. Use of ER should be discouraged.
- History • Ocular • Medical • Family
- Eye Exam: • IOP • Vision • Lens • Dilated Exam of retinal periphery
- No Tear ▶ Review if new signs and symptoms suggesting progression (may be performed by primary eye care professional)
- Acute Tear Found ▶ Refer to ophthalmologist capable of treating w/in 24hr
- Detachment Found ▶ Immediate referral

**Retinal Detachment**
- Ocular Assessment:
  - History • Vision • Lens Status • IOP
  - Dilated exam with indirect Ophthalmoscope + Scleral depression or contact lens
- Discussion of surgical options as appropriate:
  1. Pneumatic retinopexy
  2. Vitrectomy + gas
  3. Scleral buckle
  4. Vitrectomy + Scleral buckle
  5. Laser
- Informed consent

**Retinal Tear**
- • Nature and duration of symptoms
  • Ocular history
  • Medications and allergies
  - Ocular Exam, IOP, dilated fundus exam with scleral depression or wide angle contact lens exam
  - Informed consent for repair

**Preoperative Process**
- Identify Side
- Surgical Pause
- Anesthesia
- Povidone Prep/Drape
- Procedure
- Discharge Instructions

**Intraoperative Process**
- Laser
  - Anesthetic
  - Safety glasses for observers
  - 2-3 rows of contiguous burns
- Cryo
  - Anesthetic
  - Single freeze thaw “burn” around tear

**Follow-up Care**
- Follow up by surgeon within 12-36hrs:
  • Vision
  • IOP
  • Lens Status
  • Dilated Fundus Exam
- Interval monitoring with final assessment to be determined by patient progress.
- Final Assessment to include vision, IOP and DFE with scleral depression or wide angle contact lens exam.
- Communication back to F0 and others involved in care regarding what to look for
- Written communication in appropriate language to patient regarding s/s of concern
6.4 **Vitreomacular Traction, Macular Holes and Epiretinal Membranes**

These indications together are the most common indications for vitrectomy. Although surgery for these indications is elective there is good evidence in the case of macular hole surgery that delay reduces the chance of a successful outcome.

**FIGURE 15 - Treatment Inclusion Criteria and Protocol for Vitreomacular Traction, Macular Holes, and Epiretinal Membranes**

<table>
<thead>
<tr>
<th>Preop Process</th>
<th>Intraop Process</th>
<th>Follow-up Care</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discussion of findings and treatment options may include: - Observation (good acuity, minimal symptoms) - Observation (very poor acuity) - Surgery 1) ERM (progressive symptoms) 2) Macular Hole 3) Symptomatic VMT</td>
<td>Risks/benefit discussion Informed consent Identification of operated eye Surgical Pause: Anesthesia Povidone prep/Drape 3 port Pars Plana Vitrectomy +/-Epiretinal membrane/ILM removal +/-Air fluid gas exchange Written and verbal discharge instructions</td>
<td>Follow up by surgeon within 12-36 Hours: Vision, IOP, Lens Status, Dilated fundus exam Interval monitoring with final assessment to be determined by patients progress Periodic communication to family physician, referring Ophthalmologist/optometrist</td>
</tr>
</tbody>
</table>

The introduction and recent Canadian approval of Ocriplasmin (Jetrea) has provided another approach to treat selected cases of vitreomacular traction and small macular hole with an intraocular injection. Very specific criteria (hole size, presence of epiretinal membrane, and width of vitreomacular adhesion) must be met before the use of the drug should be considered so the impact of this on the demand for vitreoretinal surgery remains to be determined as it appears that only a small subset of patients may benefit.
6.5 **POST-OPERATIVE ENDOPHTHALMITIS**

While post-operative endophthalmitis is rare with expected incidence less than 1 in 1000 cataract surgery cases, the outcome often results in severe visual impairment particularly if diagnosis and treatment is delayed. Patients typically present with reduced vision and new onset pain in an eye which had been comfortable and which was seeing well. Rapid access to care, including rapid provision of specially prepared antibiotics which are injected into the eye is critical to achieving a good outcome as the disease may progress to irreversible damage within hours. Care in some cases requires immediate access to an operating room for an urgent vitrectomy.

**FIGURE 16 - Treatment Inclusion Criteria and Protocol for Acute Post-Cataract Surgery Endophthalmitis (Within 6 Weeks Post Cataract Surgery)**

<table>
<thead>
<tr>
<th>Initial Assessment</th>
<th>Cataract surgery post-operative visit:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Vision</td>
</tr>
<tr>
<td></td>
<td>IOP</td>
</tr>
<tr>
<td></td>
<td>Anterior Segment</td>
</tr>
<tr>
<td></td>
<td>Dilated Fundus</td>
</tr>
<tr>
<td></td>
<td>Refer if diagnosis of endophthalmitis is suspected. Signs and symptoms may include:</td>
</tr>
<tr>
<td></td>
<td>decreased vision</td>
</tr>
<tr>
<td></td>
<td>pain (absent in 25% of pts)</td>
</tr>
<tr>
<td></td>
<td>lid edema</td>
</tr>
<tr>
<td></td>
<td>conjunctival chemosis/erythema</td>
</tr>
<tr>
<td></td>
<td>corneal edema</td>
</tr>
<tr>
<td></td>
<td>exaggerated anterior chamber inflammation</td>
</tr>
<tr>
<td></td>
<td>hypothenar (absent in 25% of pts)</td>
</tr>
<tr>
<td></td>
<td>vitritis</td>
</tr>
<tr>
<td></td>
<td>retinal periphlebitis</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Preemptive Process</th>
<th>Medical History</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>History of visual change</td>
</tr>
<tr>
<td></td>
<td>Complete Eye Exam:</td>
</tr>
<tr>
<td></td>
<td>Vision, IOP, Lens Implant Status, Dilated Fundus Exam</td>
</tr>
<tr>
<td></td>
<td>+/- B-Scan (if view of fundus is not obtained)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Treatment</th>
<th>If visual acuity is light perception</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Vitreous culture</td>
</tr>
<tr>
<td></td>
<td>Pars Plana Vitrectomy</td>
</tr>
<tr>
<td></td>
<td>Intravitreal Antibiotic Injection:</td>
</tr>
<tr>
<td></td>
<td>Vancomycin</td>
</tr>
<tr>
<td></td>
<td>Ceftazidime</td>
</tr>
<tr>
<td></td>
<td>+/- Intravitreal steroid injection- Dexamethasone</td>
</tr>
<tr>
<td>If visual acuity is Hand Motions or better*</td>
<td>Vitreous culture (via needle tap/aspirate)</td>
</tr>
<tr>
<td></td>
<td>Intravitreal Antibiotic Injection:</td>
</tr>
<tr>
<td></td>
<td>Vancomycin</td>
</tr>
<tr>
<td></td>
<td>Ceftazidime</td>
</tr>
<tr>
<td></td>
<td>+/- Intravitreal steroid injection- Dexamethasone</td>
</tr>
<tr>
<td>If visual acuity or clinical picture not improving 48 hrs post intravitreal injections</td>
<td>Physician option</td>
</tr>
<tr>
<td></td>
<td>for repeated intravitreal antibiotic injections</td>
</tr>
<tr>
<td></td>
<td>for pars plana vitrectomy with intravitreal antibiotic injections</td>
</tr>
<tr>
<td></td>
<td>also consider reculturing of specimen</td>
</tr>
</tbody>
</table>

| Follow-up Care | Endophthalmitis should be managed in conjunction with a vitreoretinal surgeon |

*Vitrectomy may be indicated in some cases depending on the clinical situation*
7. QBP INCLUSION AND EXCLUSION GROUPS

7.1 HOSPITAL PROCEDURE GROUPS

The Advisory Group has been able to isolate five procedure groups to identify patients undergoing vitreoretinal surgery who may be included in the hospital-funded portion of the Integrated Retinal QBP. The following section defines each of these patient groups and their associated CIHI codes. The inclusion group includes day surgery patients only.

**GROUP 1 Vitrectomy without cataract:**
Includes the following procedures to remove the vitreous from the eye using posterior approach*:
- Vitrectomies using posterior approach with silicone oil replacement: **1.CM.89.PF-G2**
- Vitrectomies using a posterior approach with gas replacement: **1.CM.89.PF-V0**
- Vitrectomy using a posterior approach with balanced salt solution: **1.CM.89.PF**

Procedures in Group 1 have no associated cataract codes (1.CL.89**) in the same episode, however, in some instances they may be performed in conjunction with other ophthalmic procedures such as glaucoma procedures or lid procedures.

(*Vitrectomies using anterior approach are not included)

**GROUP 2 Scleral Buckle:**
Includes procedures for:
- Implantation of a device on the sclera (1CD53*)
- Adjustment of a device on the sclera (1CD54*)
- Removal of a device on the sclera (1CD55*)

Does not include scleral buckles related to radiation plaque (1CZ26JA).

**GROUP 3 Combined Vitrectomy and Scleral Buckle:**
This group of patients meets the criteria for both the above mentioned groups combined. **Cases that qualify for both groups 1 and 2 are counted in group 3 and not in groups 1 or 2.**

**GROUP 4 Combined Vitrectomy and Cataract:**
This group of patients meets the criteria listed above for Vitrectomy but also have a cataract procedure coded (1.CL.89*).

**GROUP 5 Combined Vitrectomy, Scleral Buckle, and Cataract:**
This is a small group of patients that meets the criteria listed above for Vitrectomy and Scleral Buckle but also have a cataract procedures coded (1.CL.89*).
*Cataract surgeries which meet the definition of the Cataract QBP are excluded from the Retina QBP.

**Scleral buckles performed in conjunction with cataract surgery are rare; however, any instances of this combination would be counted under Group 2.

**EXCLUSIONS**

- Patients 17 years and under
- Procedures performed in pediatric hospitals.
- Cataract surgeries as defined by the Cataract QBP.
- Cases with a procedure code for radiation plaque.
- Inpatient retinal surgery procedures.

Recognizing that some cases are more complex than others, the QBP pricing will require an acuity or resource adjustments which will be reviewed at one-year.

It should be noted that day surgery for retinal tears and detachments, ocular trauma and infections performed on an urgent and emergency basis are included in the Integrated Retinal QBP as there is no effective way to separate them from elective procedures in the database. The Advisory Group strongly recommends a one-year review of this inclusion to ensure that access to these urgent and emergent procedures is maintained.

**7.2 CODING CRITERIA TO IDENTIFY DAY SURGERY CASES FOR THE HOSPITAL PORTION OF THE INTEGRATED RETINAL QBP**

**INCLUDE:**
• Adults 18 years and older.
• Cases with at least one of the retinal surgery interventions in the table below. All interventions.
• Outpatient Cases identified from the National Ambulatory Care Reporting System (NACRS) where the patient category is day surgery, i.e. the MIS Visit Functional Centre code begins with "7126" or "7136".
• The health card issuing province is Ontario and Ontario is responsible for payment. i.e., Province issuing HCN= "ON" and responsibility for payment = ‘01’.
• Outpatient cases in CACS groups C064 - Vitrectomy/Retinal Release, C063 – Repair Retinal Tear Release, or C056 – Other Major eye intervention.

Table 3: Included Retinal Procedure Codes

<table>
<thead>
<tr>
<th>Description</th>
<th>CCI Codes</th>
<th>With</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Scleral Buckle Codes</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Implantation of internal device, sclera</td>
<td>1.CD.53.LA.KS</td>
<td>sceral implant</td>
</tr>
<tr>
<td></td>
<td>1.CD.53.LA.KT</td>
<td>sceral buckle [explant]</td>
</tr>
<tr>
<td>Management of internal device, sclera</td>
<td>1.CD.54.LA.KT</td>
<td>sceral buckle [explant]</td>
</tr>
<tr>
<td>Removal of device, sclera</td>
<td>1.CD.55.LA.KS</td>
<td>sceral implant</td>
</tr>
<tr>
<td></td>
<td>1.CD.55.LA.KT</td>
<td>sceral buckle [explant]</td>
</tr>
<tr>
<td><strong>Vitrectomy Codes</strong></td>
<td>1.CM.89.PF</td>
<td>balanced salt solution</td>
</tr>
<tr>
<td></td>
<td>1.CM.89.PF-G2</td>
<td>silicone oil replacement</td>
</tr>
<tr>
<td></td>
<td>1.CM.89.PF-V0</td>
<td>gas replacement †</td>
</tr>
<tr>
<td></td>
<td></td>
<td>† e.g. nitrogen, per fluorocarbon, per fluoropropane, sulfur hexafluor.</td>
</tr>
</tbody>
</table>

**EXCLUDE:**
• Patients 17 years and under.
• Procedures performed in pediatric hospitals.
• Cataract surgeries as defined by the Cataract QBP.
• Cases with a procedure code for radiation plaque (1CZ26JA).
• Abandoned and out-of-hospital retinal interventions are excluded.
• Inpatient retinal surgery cases.
8. FACTORS AND IMPLICATIONS OF AN INTEGRATED RETINA QBP

Retinal Coding and Data
Interventional care of retinal disease encompasses a large volume of care episodes which are office, clinic, day surgery, and/or operating room based. All of the activities associated with the retinal care pathways described here, are incompletely captured because of the variety of locations in which the procedures are done.

Currently, office based procedures can only be tracked within the system through OHIP codes and the ODB database, neither of which is specific enough to clearly identify all retinal care activities outlined in this clinical handbook.

The clinic and surgical care are provided mostly in hospitals although a moderate volume of elective retinal surgery is done in an IHF setting.

While admissions and surgical interventions can be tracked using CIHI data, hospitals do not separate dollars associated with retinal care from the overall ophthalmology budgets. Currently, funding for hospital based retinal interventions comes from the hospital global funding base.

Furthermore, CIHI data does not account for the complexity of the surgery. They do not allow for the differentiation of the patients who require surgical adjuvants (such as silicone oil, perfluorodecalin, intraocular laser, or special lighting systems) from patients with the same diagnosis who do not require these adjuvants. Each of these elements costs several hundred dollars therefore their use has a significant impact on cost.

Some improvements to the quality of the data can be achieved through internal coding reviews. As such, it is very important that as the Integrated Retinal QBP is introduced, ophthalmologists and coding departments in hospitals work together to ensure alignment of clinical practice to coding practice.

We strongly encourage hospitals with retinal programs, working with ophthalmologists in their organizations, to undertake Data Quality Improvement initiatives over the next 12 months.

Retinal Detachments
Much of elective retinal surgery is analogous to cancer surgery in that there is a clear time window within which the surgery must be done to provide an optimal outcome. The data that the advisory group reviewed indicates that at least 78% of inpatient retinal care and about 40% of outpatient surgical retinal care is provided to repair retinal detachments.

Care for retinal detachments requires rapid access to an operating room on an urgent (scheduled) or emergent (emergency board) basis. Accommodation of these patients requires flexibility in scheduling and the ability to deal with comorbid conditions which is difficult to achieve in an IHF.

Model of Care
Currently most, but not all, of the province’s surgical retinal care is provided at academic health sciences centers. The current volumes of medical and surgical retina care at academic institutions in Ontario are an integral part of the 5 Ophthalmology teaching programs in the province and support their teaching and
academic mission. Any new funding models should continue to support sustainable delivery of retina care at academic ambulatory and tertiary care centres in order to preserve medical education and research.

There are retinal centers in peripheral communities that provide elective, as well as urgent/emergent care. Preserving their viability is equally important, such that timely and geographically reasonable access to retina care is maintained, despite lower volumes than the highly specialized academic centres.

**IMPLICATIONS**

Consideration of the foregoing factors highlights the following implications for the development and implementation of a retinal QBP:

1. **QBP must account for complexity while avoiding inappropriate incentives:**
   The Advisory Group recognizes that our mandate was to provide evidence and recommendations to inform a separate process of costing, pricing, and payment methodology to be led by the Ministry. However, the Advisory Group emphasizes that the clinical recommendations need to be supported by a QBP funding system for hospitals that takes into consideration factors above such as the case mix and resource variation necessary to treat retina patient population and that avoids creating inappropriate incentives.

   When defining retina patient groups based on utilization, there is the potential for unintended incentives to be created when these groups are assigned prices in a funding methodology. If different prices are assigned to distinct retinal procedure groups, the funding system must be designed to provide appropriate and more accurate data collection to ensure that facilities are not incentivized to alter care or coding in an effort to increase the funding they receive.

2. **Advisory Group input into the pricing process is recommended along with a formal QBP review process after one year of implementation:**
   The Advisory Group strongly feels that our clinical and administrative expertise will assist the Ministry in developing appropriate hospital pricing strategies for the Integrated Retinal QBP.

   It is critical that pricing decisions be made on the most accurate CIHI data and which as noted above, we expect to improve over the next year as hospitals and ophthalmologists start to work with the QBP clinical handbook. For this reason, we also recommend that the Integrated Retinal QBP costing and funding rates be reviewed and adjusted if necessary, in the year following implementation.

3. **QBP model must account for shifting urgent care volumes year to year:**
   Urgent retina volumes and complexity may vary considerably from year to year at both an institutional level as well as a provincial level. As a result, some hospitals may receive a greater proportion of transferred cases from other hospitals. It is therefore imperative that the QBP funding model accommodate these shifts and fluctuations in volume from year to year.

**9. PERFORMANCE MEASUREMENT**
The Ministry requested that, as part of the work of the Integrated Retinal QBP, the Advisory Group develop recommendations around performance indicators. The intent is for these performance indicators to be aligned with the recommended practices for the episode of care. This will allow the Ministry to measure the improvements in quality of care that result from the implementation of the Quality-Based Procedures (QBP). The Ministry has proposed an “Integrated Scorecard” that would gather similar indicators from each of the QBP clinical areas.


Indicators were selected to reflect some key best-practice surrogates, which may provide a foundation for ensuring that hospitals are adhering to some general evidence-based principles across the integrated retina pathway. The Expert Panel selected 8 indicators that are considered developmental.

Table 4: Recommended Performance Metrics

<table>
<thead>
<tr>
<th>Domain (QBP Goal)</th>
<th>What is being measured?</th>
<th>Clinical Expert Advisory Group Recommended Indicators</th>
<th>Level of Monitoring</th>
</tr>
</thead>
</table>
| Effectiveness    | • What are the outcomes of care?  
                  • Do results vary across providers?  
                  • Can variation be explained by population characteristics?  
                  • Is care provided without causing harm? | • Incidence of post-injection infection/ inflammation  
                                                       • Incidence of post-operative infection/ inflammation | • LHIN  
                                                       • Organization  
                                                       • Clinical |
| Appropriateness  | • Is patient care being provided according to scientific knowledge and in a way that avoids overuse, underuse and misuse? | • Percentage of patients who stop Anti-VEGF treatment within a year of treatment start date. Collected by retinal disease type. | • LHIN  
                                                       • Organization  
                                                       • Clinical |
| Integration      | • Are all parts of the health system organized, connected, and work with one another to provide quality care? | • Percentage of patient with diabetes who have a retinal eye exam the past year. | • LHIN  
                                                       • Organization  
                                                       • Clinical |
| Efficiency       | • Does the system make good use of its resources to yield maximum benefit ensuring that the system is sustainable for the long-term? | • Percentage of in-patients vs. day surgery patients – by retinal procedures.  
                                                       • Number of cases performed after-hours. | • LHIN  
                                                       • Organization  
                                                       • Clinical |
| Access           | • Are those in need of care able to access services when needed? | • The aggregate wait time of Wait 1 (time from referral receipt to specialist assessment) and Wait 2 (time from decision to treat to surgery date). | • LHIN  
                                                       • Organization  
                                                       • Clinical |
| Patient Experience| • Domain Under Development | • Modified patient questionnaire to be determined. | • LHIN  
                                                       • Organization  
                                                       • Clinical |

Further to the performance metrics that are outlined above, the Advisory Group identified additional performance metrics which our system does not currently have the infrastructure to support but would
provide meaningful feedback on the quality of patient care should they be implemented as a long-term goal. These aspirational metrics are:

- **Integration metric**: Percentage of diabetes patients referred to optometry or ophthalmology for follow-up.

- **Access metric**: ER – Ophthalmology, time to consult.

- **Access metric**: Number of Retinal Detachment cases performed after-hours.

**Recommendations for the Implementation of the Performance Indicators**

In developing these performance indicators the Advisory Group discussed the importance of Quality reporting, particularly as it relates to the incidence of infection/severe inflammation. There has been at least one outbreak of inflammation linked to intraocular injection in Ontario in the past. Because injections are largely office based the usual hospital based recognition and reporting/control mechanisms were ineffective. It is recommended that the reporting of office or clinic based infection/inflammation would be centrally monitored within each LHIN to allow for effective identification of outbreaks and compromises to good quality care. The mechanism by which this reporting is centralized would LHIN-specific; however, the Advisory Group suggested that a lead facility could be appointed in each of the LHINs to coordinate the initiative.
### 10. ADVISORY GROUP MEMBERSHIP

<table>
<thead>
<tr>
<th>NAME</th>
<th>LHIN</th>
<th>AFFILIATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr. Phil Hooper (Co-Chair)</td>
<td>SW LHIN</td>
<td>Retinal Specialist, Associate Professor, Ophthalmology; Ophthalmology Lead, Ontario Wait Time Program</td>
</tr>
<tr>
<td>Dr. Sherif El-Defrawy (Co-Chair)</td>
<td>TC LHIN</td>
<td>General Ophthalmology; Professor and Chair, Department of Ophthalmology and Vision Sciences, University of Toronto</td>
</tr>
<tr>
<td>Dr. Bernard Hurley</td>
<td>CHMP LHIN</td>
<td>Retina Specialist (Medical/Surgical – The Ottawa Hospital)</td>
</tr>
<tr>
<td>Dr. Michael Brent</td>
<td>TC LHIN</td>
<td>Retina Specialist (Medical - UHN)</td>
</tr>
<tr>
<td>Dr. Sanjay Sharma</td>
<td>SE LHIN</td>
<td>Retina Specialist (Medical/Surgical - Kingston)</td>
</tr>
<tr>
<td>Dr. Peter Kertes</td>
<td>TC LHIN</td>
<td>Retina Specialist (Medical/Surgical – Sunnybrook)</td>
</tr>
<tr>
<td>Dr. Alan Berger</td>
<td>TC LHIN</td>
<td>Retina Specialist (Medical/Surgical – St. Mike’s)</td>
</tr>
<tr>
<td>Dr. Varun Chaudhary</td>
<td>HNHB LHIN</td>
<td>Retina Specialist (Medical/Surgical – St. Joe’s Hamilton)</td>
</tr>
<tr>
<td>Dr. Natalia Baziuk</td>
<td>CE LHIN</td>
<td>Retina Specialist (Medical/Surgical – Lakeridge)</td>
</tr>
<tr>
<td>Dr. Alejandro Oliver</td>
<td>NE LHIN</td>
<td>Retina Specialist (Medical/Surgical – Timmins)</td>
</tr>
<tr>
<td>Dr. Jordan Cheskes</td>
<td>CE LHIN</td>
<td>Retina Specialist (Medical/Surgical – Scarborough)</td>
</tr>
<tr>
<td>Dr. Warren Bradley Kates</td>
<td>MH LHIN</td>
<td>Retina Specialist (Medical Retina Large Community – Oakville)</td>
</tr>
<tr>
<td>Dr. Mark Bariciak</td>
<td>NE LHIN</td>
<td>General Ophthalmology; (Medical Retina Rural/Northern – Sault Ste. Marie)</td>
</tr>
<tr>
<td>Dr. Mario Ventresca</td>
<td>HNHB LHIN</td>
<td>General Ophthalmology; (Medical Retina Small Community – Port Colborne)</td>
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<tr>
<td>Dr. Rob Campbell</td>
<td>SE LHIN</td>
<td>ICES Scientist, Ophthalmology</td>
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<tr>
<td>Dr. Chaim Bell</td>
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<td>ICES Scientist, Ophthalmology</td>
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<tr>
<td>Dr. Eric Goldszmidt</td>
<td>TC LHIN</td>
<td>Anesthetist (Mount Sinai)</td>
</tr>
<tr>
<td>Dr. Kylen McReelis</td>
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<td>General Ophthalmology; Tariff Chair, Eye Physicians and Surgeons Ontario</td>
</tr>
<tr>
<td>Chris Judd</td>
<td>SW LHIN</td>
<td>Pharmacy; Director, St. Joseph’s Health Care</td>
</tr>
<tr>
<td>Craig Simms</td>
<td>SE LHIN</td>
<td>Clinical Manager, Ophthalmology, Hotel Dieu Kingston</td>
</tr>
<tr>
<td>Jill Tettmann</td>
<td>NSM LHIN</td>
<td>CEO, NSM LHIN</td>
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<tr>
<td>Cameron Love</td>
<td>CHMP LHIN</td>
<td>Administrator, Sr. VP, Clinical Programs, Planning and Support Services, TOH</td>
</tr>
<tr>
<td>Marnie Weber</td>
<td>TC LHIN</td>
<td>Administrator; Executive Director, Strategic Developments, UHN</td>
</tr>
<tr>
<td>Dr. Nicole Nitti</td>
<td>TC LHIN</td>
<td>Diabetes, Primary Care Lead</td>
</tr>
<tr>
<td>Dr. Jennifer Everson</td>
<td>HNHB LHIN</td>
<td>Primary Care Lead, HNHB LHIN</td>
</tr>
<tr>
<td>Dr. Thomas Noel</td>
<td>CHMP LHIN</td>
<td>Optometrist</td>
</tr>
<tr>
<td>Michael Stewart</td>
<td>Provincial</td>
<td>Lead, Decision Support and Knowledge Transfer, MOHLTC</td>
</tr>
<tr>
<td>Brent Fraser</td>
<td>Provincial</td>
<td>Director, Drug Program Services, MOHLTC</td>
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<tr>
<td>Justine Humphries</td>
<td>TC LHIN</td>
<td>Project Lead</td>
</tr>
<tr>
<td>Joanna Li</td>
<td>TC LHIN</td>
<td>Health Coding Analyst, Decision Support, University Health Network</td>
</tr>
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## 11. Methodology Group Membership

<table>
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<tr>
<th>NAME</th>
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<tr>
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<td>Clinical Expert</td>
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<td>Clinical Expert</td>
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<td>Administrator</td>
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<td>Justine Humphries</td>
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<td>Project Lead; UHN</td>
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<tr>
<td>Elizabeth Chiu</td>
<td>TC LHIN</td>
<td>Manager, Coding and Abstracting; UHN (Academic Hospital)</td>
</tr>
<tr>
<td>Connie Fleese</td>
<td>MH LHIN</td>
<td>Manager, Coding and Data Quality; Trillium Health Partners (Community Hospital)</td>
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<tr>
<td>Brent Fraser</td>
<td>Provincial</td>
<td>Director, Drug Program Services, MOHLTC</td>
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<tr>
<td>Anubha Prashad</td>
<td>Provincial</td>
<td>Senior Policy Consultant, Health Quality Branch, MOHLTC</td>
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<tr>
<td>Audrey Pereira</td>
<td>Provincial</td>
<td>Health Analyst, Methods and Modeling, Health Analytics Branch, MOHLTC</td>
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<tr>
<td>Jane Chen</td>
<td>TC LHIN</td>
<td>Case Costing; Academic Hospital; UHN</td>
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<tr>
<td>Kamil Malikov</td>
<td>Provincial</td>
<td>Manager, Methods and Modeling, Health Analytics Branch, MOHLTC</td>
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**APPENDIX 1 – ACRONYM LEGEND**

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<tr>
<th>Acronym</th>
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<td>AMD</td>
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<td>BRVO</td>
<td>Branch Retinal Vein Occlusion</td>
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<td>CCAC</td>
<td>Community Care Access Centre</td>
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<td>CME</td>
<td>Central Macular Edema</td>
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<td>COS</td>
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<td>HSFR</td>
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<td>IOP</td>
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<td>IVFA</td>
<td>Intravenous Fluorescein Angiography</td>
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<td>NACRS</td>
<td>National Ambulatory Care Reporting System</td>
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<td>NVA</td>
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<td>Neovascularization of the Disk</td>
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<td>NVE</td>
<td>Neovascularization Elsewhere</td>
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<td>NVG</td>
<td>Neovascularization Glaucoma</td>
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<td>NVI</td>
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<td>OCCI</td>
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<td>OHTAC</td>
<td>Ontario Health Technology Advisory Committee</td>
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<td>PDR</td>
<td>Proliferative Diabetic Retinopathy</td>
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<td>PRN</td>
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