MULTIPLE MYELOMA
PRECURSOR CONDITIONS

Monoclonal Gammopathy of Undetermined Significance and Smoldering Multiple Myeloma

Contact one of our Patient Navigators at the Patient Navigation Center
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Hours: Mon–Fri, 9 AM–7 PM ET

Email: patientnavigator@themmrf.org

Multiple Myeloma Research Foundation
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ABOUT THE MULTIPLE MYELOMA RESEARCH FOUNDATION

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INTRODUCTION

Patients with multiple myeloma typically have a preceding phase of disease in which there are changes in the bone marrow but no symptoms or organ damage. The diseases that occur in this phase are monoclonal gammopathy of undetermined significance (MGUS) and smoldering multiple myeloma (SMM) (also called asymptomatic myeloma), collectively known as myeloma precursor conditions.

This booklet has been developed to help patients with SMM, MGUS, or multiple myeloma—as well as their friends, families, and caregivers—better understand the myeloma precursor conditions. Words that may be unfamiliar are bolded and defined in the Glossary (page 10).

The information in this booklet is not intended to replace the services or advice of trained health care professionals. Please consult with your health care provider regarding specific questions relating to your health, especially questions about myeloma diagnosis or treatment.

For more information about multiple myeloma and its treatment, please refer to the companion booklets (Multiple Myeloma Disease Overview, Multiple Myeloma Treatment Overview, Multiple Myeloma Autologous Stem Cell Transplantation, Multiple Myeloma Immunotherapy, and The Path to Precision Medicine) and the MMRF website (www.themmrf.org).
MULTIPLE MYELOMA PRECURSOR CONDITIONS

Almost all patients diagnosed with multiple myeloma have had a preceding phase of disease that is characterized by changes in the bone marrow. Depending on the nature of these changes, this disease phase is known as monoclonal gammopathy of undetermined significance (MGUS) or smoldering multiple myeloma (SMM); collectively, these are known as myeloma precursor conditions. Patients with MGUS or SMM do not experience the symptoms or organ damage that are commonly associated with multiple myeloma, such as osteolytic lesions (also called lytic or bone lesions), fractures, and kidney failure.

In both MGUS and SMM, plasma cells in the bone marrow grow more rapidly than normal. These rapidly growing plasma cells, which can develop into myeloma cells, produce monoclonal protein (or M protein), a substance that is detectable in the blood or urine. Both precursor conditions differ from multiple myeloma in that no tumors or bone lesions develop, there are no symptoms or signs of active disease (such as anemia), and no criteria used to make a myeloma diagnosis are present.

Multiple myeloma precursor conditions.
Some patients learn that they have MGUS or SMM when M protein is detected in their blood or urine. Because most people are not screened for these precursor conditions (doctors do not routinely order tests to measure M protein) and there are no signs or symptoms associated with either condition, diagnosis of MGUS or SMM usually only happens incidentally—when a doctor investigating another health issue happens to discover M protein in the blood or urine.

For more information about how a diagnosis of multiple myeloma is made, please refer to the companion booklet *Multiple Myeloma Disease Overview* and the MMRF website ([www.themmrf.org](http://www.themmrf.org)).

Many patients who have one of the myeloma precursor conditions remain undiagnosed for several years.

**PRECURSOR CONDITIONS AND THE RISK OF PROGRESSING TO MULTIPLE MYELOMA**

Multiple myeloma, a cancer of the plasma cells, is part of a disease spectrum; it is the last stage of a process that generally begins with MGUS and progresses to SMM before advancing to myeloma.

The multiple myeloma disease spectrum.
MGUS occurs in less than 1% of the general population and in about 3% of healthy individuals over 50. The prevalence is two to three times higher in the Black* community for reasons that are unknown. Also, people who have a first-degree relative with a blood cancer (not just myeloma) are at a higher risk of having MGUS.

MGUS almost always occurs before a person develops myeloma; it is associated with a risk of progression to myeloma of approximately 1% per year. MGUS progresses to multiple myeloma or another malignant plasma cell disease (lymphoma or amyloidosis) in 10% of individuals with the condition at 10 years, 18% at 20 years, 28% at 30 years, 36% at 35 years, and 36% at 40 years. MGUS can also be associated with other diseases, including osteoporosis.

SMM is a stage between MGUS and multiple myeloma, and it is associated with a higher risk relative to MGUS of progression to myeloma: approximately 10% per year for the first 5 years; however, progression varies among patients.

DIAGNOSIS

When an individual is found to have M protein in the blood or urine, the doctor will conduct tests to find out where on the spectrum of disease the patient resides—that is, whether the patient has MGUS, SMM, or multiple myeloma. Blood, urine, bone marrow, and imaging tests can help identify which condition a patient has. The level of M protein in the blood or urine and the percentage of plasma cells in the bone marrow differ between each condition, with MGUS having lower amounts of both than SMM. Neither condition is associated with the clinical features characteristic of multiple myeloma, such as calcium elevation, renal insufficiency (kidney problems), anemia (low levels of red blood cells), and bone fractures or lesions—these are often referred to by doctors as the CRAB criteria. Additionally, neither condition meets any of the SLiM criteria used by doctors to diagnose myeloma: sixty percent or more plasma cells in the bone marrow, an elevated free light chain ratio, and more than one bone lesion as determined by magnetic resonance imaging (MRI), positron emission tomography (PET), or computed tomography (CT) scan.

*The terms Black and African American are used interchangeably in this booklet to refer to people of African descent currently residing in the US, regardless of their nationality or country of birth.
Blood, urine, bone marrow, and imaging tests used to identify MGUS, SMM, or multiple myeloma.

<table>
<thead>
<tr>
<th></th>
<th>MGUS</th>
<th>SMM</th>
<th>Multiple myeloma</th>
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<tbody>
<tr>
<td><strong>M protein</strong></td>
<td>&lt;3 g/dL in blood</td>
<td>≥3 g/dL in blood</td>
<td>≥3 g/dL in blood</td>
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<td></td>
<td></td>
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<td></td>
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<td>≥500 mg/24 hrs in urine</td>
<td>≥500 mg/24 hrs in urine</td>
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<tr>
<td><strong>Plasma cells in bone marrow</strong></td>
<td>&lt;10%</td>
<td>≥10%–60%</td>
<td>≥60%</td>
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<tr>
<td><strong>Clinical features</strong></td>
<td>No myeloma-defining events*</td>
<td>No myeloma-defining events*</td>
<td>≥1 myeloma-defining event*, including either:</td>
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<td></td>
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<td>• ≥1 CRAB feature</td>
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<td>• ≥1 SLiM feature</td>
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</tbody>
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*CRAB, calcium elevation, renal insufficiency, anemia, bone disease; SLiM, >60% plasma cells in bone marrow; free light chain involved to uninvolved ratio >100; >1 focal lesion on MRI

**HIGH-RISK SMM**

Some patients with SMM are more likely to develop myeloma than others, and a new risk-stratification model has been developed to determine which patients with SMM are at high risk for progression to myeloma. High risk is determined based on the presence of two or more specific risk factors as determined through blood and bone marrow testing. This method of assessing risk uses what is referred to as a 2/20/20 risk-stratification model, named for the key test values that define high risk.
The 2/20/20 risk-stratification model for SMM patients.

<table>
<thead>
<tr>
<th>Risk assessment for SMM*</th>
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<tr>
<td><strong>2</strong></td>
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<tr>
<td>&gt;2 g/dL M protein</td>
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<tr>
<td><strong>20</strong></td>
</tr>
<tr>
<td>&gt;20 free light chain ratio</td>
</tr>
<tr>
<td><strong>20</strong></td>
</tr>
<tr>
<td>&gt;20% bone marrow plasma cells</td>
</tr>
</tbody>
</table>

*Patients with two or more risk factors are considered high risk. This model does not include any biologic or immune factors that may account for differences between patients.

Patients with high-risk SMM have a higher risk of progressing to myeloma at 2 years (44%) than do patients with low-risk SMM (6%).

**HOW AND WHEN TO TREAT MYELOMA PRECURSOR CONDITIONS**

The standard of care for patients with MGUS or SMM is watchful waiting—that is, monitoring patients closely to determine if they progress to myeloma and treating them only when progression occurs. The reason patients with MGUS or SMM are not treated is that neither condition is associated with organ damage or any of the symptoms commonly associated with myeloma. Furthermore, no more than half of SMM patients progress to myeloma within the first 5 years after diagnosis, and the number is even smaller for patients with MGUS. Additionally, administering myeloma treatments to patients who have precursor conditions that may or may not advance to multiple myeloma could lead to unwanted side effects while also yielding no benefit.

High-risk smoldering multiple myeloma may warrant treatment rather than watchful waiting and may yield the benefits of delaying the onset of active myeloma and increasing life expectancy. Treatment, if recommended at this stage, should only take place in the context of a clinical trial.
Fortunately, there are several clinical trials for patients with normal-risk MGUS or SMM to participate in, such as the PROMISE study, the PCROWD study, and the MMRF’s CureCloud. These screening studies and observational studies are being conducted to identify patients earlier in the myeloma disease spectrum and to understand the clinical and genetic features of these precursor conditions that are associated with progression to myeloma.

For patients with intermediate- to high-risk SMM, several interventional trials (that is, trials that investigate treatments) are available that are investigating various myeloma drugs and drug combinations to prevent progression to myeloma. Early studies have shown that treatment with Revlimid prolonged the amount of time before patients with intermediate- and high-risk SMM progressed to multiple myeloma. The latest studies are investigating whether single-drug or combination therapy with some newer anti-myeloma drugs will be effective in preventing progression or lengthening the time to progression. So far, the results of these studies have been promising, and there is good reason for optimism and hope.

Patients with MGUS and SMM are typically monitored without treatment (watchful waiting) until there is evidence of disease progression. If this approach causes you anxiety, have an honest conversation with your doctor about your concerns, your risk for progression, and the possibility of joining a clinical trial.

Myeloma clinical trials can be found at clinicaltrials.gov. Or you can use the MMRF’s clinical trial finder (themmrf.org/resources/clinical-trial-finder/) to search for a clinical trial in your area.
SCREENING FOR MYELOMA PRECURSOR CONDITIONS

It has long been understood that the earlier any type of cancer is caught, the greater the chances are that treatment will be successful. Screening for cancer saves lives in other cancers, as has been shown with mammography for breast cancer and colonoscopy for colon cancer.

Identifying the individuals with MGUS or SMM who have a greater likelihood of progressing to myeloma could potentially lead to treatments that prevent that progression, which could enable those individuals to achieve longer, more durable remissions and longer life expectancy.

If you were recently diagnosed with MGUS, SMM, or multiple myeloma, don’t despair. There is ample reason for hope. New drugs and treatments are being discovered every year, and life expectancy and quality of life are improving all the time.

In the PROMISE study, a simple blood test is being used to detect a myeloma precursor condition. For each patient found to have a precursor condition, the study aims to predict the disease course and to prevent multiple myeloma from developing. Two groups of US adults (ages 40 to 75) can join PROMISE: (1) African Americans; (2) people of any race who have a parent, sibling, or child with multiple myeloma, another blood cancer, OR one of the following related conditions: MGUS, SMM, Waldenström macroglobulinemia.

The MMRF would like to thank Irene Ghobrial, MD, Lavine Family Chair of Preventative Cancer Therapy and Director of the Center for Prevention of Progression at the Dana-Farber Cancer Institute in Boston, Massachusetts, and our patient advocate, Marc Davis of Covington, Georgia, for their contributions to this booklet.
MMRF PATIENT SUPPORT AND RESOURCES

The MMRF is dedicated to supporting the myeloma community by providing a broad range of resources for myeloma patients and their family members and caregivers. The MMRF is available to help guide you through your multiple myeloma journey every step of the way.

YOUR QUESTIONS ANSWERED

Speak to an MMRF Patient Navigator at the Patient Navigation Center for answers to your questions about disease management, treatments, clinical trials, and assistance with finding financial and other available resources.

Telephone: 1.888.841.6673
Monday–Friday, 9:00 AM to 7:00 PM ET
Email: patientnavigator@themmrf.org

Connect with an MMRF Myeloma Mentor™: themmrf.org/resources/myeloma-mentors

This is a phone-based program offering the opportunity for patients and/or caregivers to connect one-on-one with a trained patient and/or caregiver mentor to share their patient journeys and experiences.

FIND AND PARTICIPATE IN A CLINICAL TRIAL

Search for a clinical trial in your area or let MMRF Patient Navigators help guide you through the process.

Clinical Trial Search: themmrf.org/resources/clinical-trial-finder

SUPPORT THE MMRF

Help support the MMRF’s efforts to accelerate research and find a cure! Participate in an event or donate today.

Telephone: 1.203.229.0464
Donate now/Take action: themmrf.org/get-involved
GLOSSARY

**amyloidosis** Disorder in which abnormal protein is deposited in organs and tissues

**anemia** Decrease in the number of red blood cells in the blood

**antibody** Protein produced by plasma cells that helps protect the body from infection and disease

**bone marrow** Soft, spongy tissue found in the center of many bones and site of blood cell production

**calcium** Mineral that is important in bone formation; elevated serum levels occur when there is bone destruction

**clinical trial** A study of the safety and effectiveness of a therapeutic agent using consenting human subjects

**colonoscopy** Imaging test of the colon

**computed tomography (CT)** Imaging technique that uses a computer to generate three-dimensional x-ray pictures (also referred to as computerized axial tomography [CAT])

**CRAB** Acronym for the following group of clinical indicators of organ damage: increased calcium level, renal (kidney) failure, anemia, bone lesions; the presence of one or more of these indicators can help establish a diagnosis of multiple myeloma

**CureCloud** A direct-to-patient research effort aimed at enrolling 5,000 individuals from whom comprehensive molecular and immune analyses will be generated from blood samples and the resulting data aggregated with the correlating clinical information

**interventional trial** Type of clinical trial in which participants receive specific interventions that may be medical products (such as drugs or devices) or procedures
light chain The shorter of two protein chains that make up an antibody, characterized as either kappa or lambda type; light chains produced by myeloma cells are also referred to as Bence Jones proteins when they occur in the urine

lymphoma Blood cancer that develops in the lymph nodes

magnetic resonance imaging (MRI) Scanning technique that uses magnetic energy to provide detailed images of bone and soft tissue

malignant Cancerous, continuing to divide

mammography Imaging test of the breast

monoclonal (M) protein Abnormal antibody found in large quantities in the blood and urine of individuals with myeloma

monoclonal gammopathy of undetermined significance (MGUS) A condition that can occur before a patient develops or shows any symptoms of multiple myeloma; indicated by the presence of M protein in the serum or urine, MGUS may eventually progress to myeloma

multiple myeloma Blood cancer that develops in the bone marrow as a result of plasma cells transforming into cancerous myeloma cells

myeloma precursor conditions Any of the preceding phases of multiple myeloma, called monoclonal gammopathy of undetermined significance (MGUS) or smoldering multiple myeloma (SMM), that are characterized by the amount of M protein in the blood and percentage of plasma cells in the bone marrow, but no symptoms or organ damage

observational study Clinical trial in which participants are observed over a period of time to assess health outcomes

osteolytic lesion Soft spot in the bone where bone tissue has been destroyed; appears as a hole in the bone on a standard x-ray

osteoporosis Bone loss typically associated with old age; can occur in myeloma
**PCROWD study** Clinical trial conducted to identify changes in the cells of patients with myeloma precursor conditions (MGUS or SMM) (visit www.enroll.pcrowd.org)

**plasma cell** Antibody-secreting immune cell that develops from a B cell; in myeloma, it is this cell that has become cancerous or abnormal

**positron emission tomography (PET)** Imaging technique in which radioactive glucose (sugar) is used to highlight cancer cells

**PROMISE study** Clinical trial conducted to identify new ways to prevent multiple myeloma in individuals with its precursor conditions (MGUS or SMM) (visit www.enroll.promisestudy.org)

**red blood cell** Blood cell that carries oxygen

**screening study** Clinical trial that evaluates new tests for detecting cancer and other health conditions in people before symptoms are present

**SLiM** Acronym for the following group of clinical indicators of multiple myeloma: sixty percent or greater plasma cells in the bone marrow; an elevated free light chain ratio; MRI with more than one bone lesion; the presence of any of these indicators establishes a diagnosis of multiple myeloma

**smoldering multiple myeloma (SMM)** Myeloma characterized by increased M protein and slightly increased numbers of plasma cells in the bone marrow and an absence of symptoms; patients with SMM are monitored and only treated if their disease progresses; also called asymptomatic myeloma

**stratification model** An analytical tool used to sort data, people, and objects into distinct groups

**Waldenström macroglobulinemia** Type of slow-growing lymphoma
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