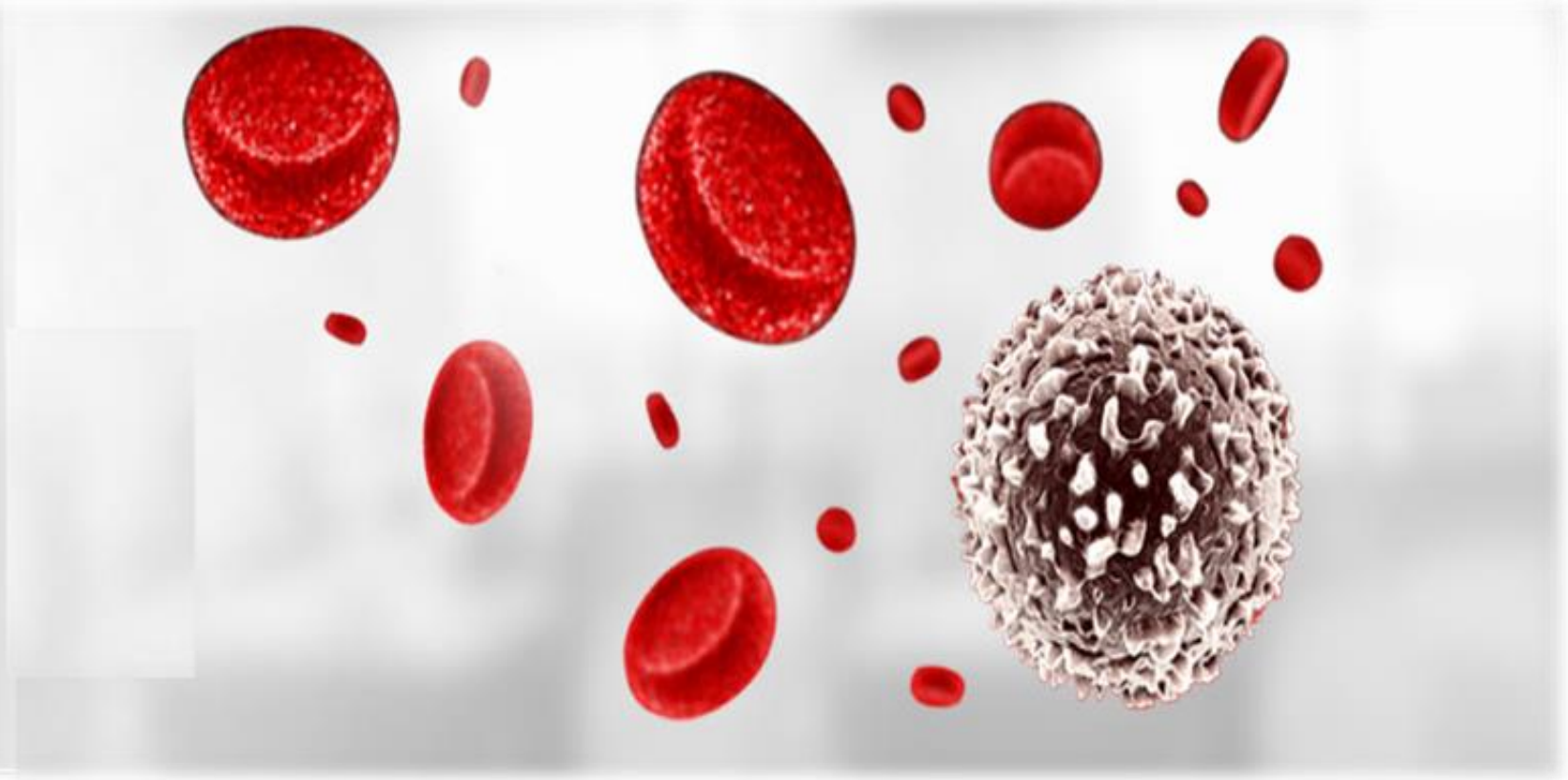
Long-term follow up module

POST-TRANSPLANT CARE

Dr. Mustafa ÇETİN

- CLINIC VISITS
- SCREENING
- IMMUNIZATION
- GVHD



Post-transplant Care and Follow Up Plan

These long-term screening guidelines are based on Recommended Screening and Preventive Practices by international experts.[1]

- *Complications from hematopoietic cell transplantation can develop from the discharge to long after a patient leaves a transplant center*
- *Early recognizing of complications is critical to manage effectively and provide the well-being of transplant recipients.*
- *Use these guidelines to deliver the specialized care transplant patients need to prevent late complications and to reduce morbidity.*

Plan I:
Clinical Visit and Screen

The patients should be followed with regular clinical visit for preventive practices.

Includes a list of recommended screening test

Consult this section at a patient's six-month, one-year and annual appointments.

Plan II:
Vaccinations

Provides a recommended vaccination schedule.

Consult this prior to a patient's six-month appointment and as needed at future appointments.

Plan III:
Screening for chronic GVHD

Identifies clinical manifestations and symptoms of chronic graft- versus-host disease (GVHD)

Consult this section when chronic GVHD is suspected or to review the full range of chronic GVHD manifestations.

Plan I: Clinical Visit and Screen

After returning home,

- *Hematopoietic transplant patients should be followed with weekly office visits for one month.*

If the patient's medical condition remains stable.

- *For six months, the interval time between visits can be extended to 2 or 3 weeks for 6 months.*
- *For one year, interval time can be extended monthly except for special clinical conditions*

Vital signs and body weight should be monitored at each clinic visit. Weight and height should be recorded at monthly intervals for assessment of growth and development in pediatric patients. Patients who have had an allogeneic hematopoietic stem cell transplant should be monitored for development of chronic graft-versus-host disease (GVHD).

Note: *Recommended screening as per general population: hypertension, hypercholesterolemia, diabetes, depression, sexually transmitted diseases, osteoporosis (in women), cancer screening.*

1Majhail NS, Rizzo JD, Lee SJ, et al. Recommended screening and preventive practices for long-term survivors after hematopoietic cell transplantation; Center for International Blood and Marrow Transplant Research (CIBMTR), American Society for Blood and Marrow Transplantation (ASBMT), European Group for Blood and Marrow Transplantation (EBMT), Asia-Pacific Blood and Marrow Transplantation Group (APBMT), Bone Marrow Transplant Society of Australia and New Zealand (BMTSANZ), East Mediterranean Blood and Marrow Transplantation Group (EMBMT) and Sociedade Brasileira de Transplante de Medula Ossea (SBTMO). Co-published in Biol Blood Marrow Transplant, 2012;18(3): 348-371; Bone Marrow Transplant, 2012 47(3): 337–341;and Hematol Oncol Stem Cell Ther, 2012;5(1):1-30.

Screen Test & Preventive Measures	Recommended Visit Timing 1. m	6. m	12 . m	24. m
Should be measured recommended period at each office visit.	W.	2W.	M	3.M.
Lab Tests				
✓ Complete Blood Cell Counts:				
Patients receiving ganciclovir (or ValGANCiclovir), daily Trimethoprim/Sulfamethoxazole (TMP/SMX), Cellcept (mycophenolate mofetil), and other myelosuppressive medication should have a CBC at weekly intervals or more often when counts are low.	√	√	√	√
✓ Liver Function Tests :				
Patients receiving immunosuppressive medications or other hepatotoxic drugs such as itraconazole, voriconazole, INH, should have LFT's measured at two-week intervals or more often when abnormalities are present. If drug toxicity suspected, blood levels should be checked if available.	√	√	√	√
✓ Renal Function Tests :				
Patients receiving cyclosporine, tacrolimus (FK506), amphotericin or other nephrotoxic drugs should have renal function monitored at weekly intervals or more often when abnormalities are present. Dose adjustment may be needed for medications such as cyclosporine, tacrolimus, ganciclovir, valacyclovir, acyclovir, among others.	√	√	√	√

Screen Test & Preventive Measures	Recommended Visit Timing 1. m	6. m	12 . m	24. m
Should be measured recommended period at each office visit.	W.	2W.	M	3.M.
Lab Tests				
✓ Fasting lipids profile :				
should be monitored initially monthly until acceptable stable values are achieved, thereafter, monitoring may be decreased to every 3 to 6 months, or more often if clinically indicated	√	√	√	√
✓ Thyroid function tests :				
should be monitored yearly due to increased thyroid disease after transplant.	√	√	√	√
✓ Serum immunoglobulins levels :				
should be monitored at 3 monthly intervals until levels remain stable and ensure the serum IgG levels above 400 mg/dL after transplant prior to start of vaccinations.	√	√	√	√

Fasting lipids profile is recommended periodically due to increased risk of cardiovascular disease and increased risk of meta bolic syndrome in transplant survivors. Especially In patients receiving sirolimus, tacrolimus or cyclosporine .

Thyroid function tests For patients who received radiolabeled iodine antibody therapy, thyroid function should be checked sooner at 3 and 6 months within the first year after transplant, and other times as clinically indicated.

Serum immunoglobulins levels should be monitored for allogeneic patients transplanted for myeloma, low grade lymphoma or CLL and Other especially haploidentical donors or cord blood and , unrelated donors transplant or for patients with ongoing infections or chronic GVHD :

Screen Test & Preventive Measures	Recommended Visit Timing 1. m	6. m	12 . m	24. m
Should be measured recommended period at each office visit.	W.	2W.	M	3.M.
Drug levels:				
✓ Cyclosporine or tacrolimus (FK506) :				
should be monitored at least twice monthly until levels remain stable within the therapeutic range.	√	√	√	√
✓ Sirolimus (rapamycin) :				
should be monitored weekly until levels remain stable within levels maintained no higher than 10 ng/dL).	√	√	√	√
✓ Itraconazole :				
should be monitored at monthly intervals until levels remain stable within the therapeutic range. Itraconazole levels should be checked more frequently when results are outside the therapeutic range and when results of LFT's are abnormal.	√	√	√	√

Sirolimus, cyclosporine or tacrolimus (FK506) levels should be checked more frequently when toxicity is suspected (i.e., newonset of thrombocytopenia, worsening anemia, abnormal renal function, abnormal LFT's, development of tremors or other neurological symptoms), when blood levels are outs ide the therapeutic range or when manifestations of GVHD is not under control.

Voriconazole, posaconazole and the other azoles should be used with caution during treatment with sirolimus. If treatment with azoles is warranted pleas e contact the LTFU office to discuss sirolimus dose adjustment.

Screen	Parameters	Preventive Measures	Recommended Visit Timing 1. m 6. m 12 . m 24. m

Organ	Test & Complications	Should be measured and evaluated recommended period at each office visit.	W.	2W.	M	3M.
Immune system	*Infections (Viral, Bacterial, Fungal and Opportunistic) 1. Preventive Tests: CMV Antigen or PCR (in patients at high risk for CMV reactivation) 2. Radiologic studies (chest X-ray, CT scan) 3. Immune System Immunoglobins and T-cell subset tests	✓ All HCT recipients (Prophylaxis)				
		Pneumocystis pneumonia (PCP) prophylaxis for initial 6 months after HCT	√	√		
		Antiviral Prophylaxis targeting CMV, VZV for initial 6 months after HCT	√	√		
		Antifungal Prophylaxis targeting mold and yeast for initial 6 months after HCT	√	√		
		✓ Additional measures for special populations*			GVHD & Steroids	
		Prophylaxis targeting PCP for the duration of immunosuppressive therapy (IST)	√	√	+	+
		Screening for CMV in patients at high risk for CMV reactivation	√	√	+	+
		Antifungal Prophylaxis targeting mold and yeast for the duration of IST	√	√	+	+

NOTE: Antimicrobial prophylaxis targeting encapsulated organisms for initial 6 months and the duration of immunosuppressive therapy ???
(American Heart Association guidelines, Visit http://circ.ahajournals.org/content/116/15/1736.full.pdf)

Key:

=recommended preventive measures

+=Assessment recommended for patients with pre-existing conditions, if clinically indicated, if abnormal testing in a previous time period, or with new signs/symptoms

*Special populations =GVHD (patients with GVHD), Steroids (patients with ongoing significant corticosteroid exposure), TBI (patients who have received total body irradiation)

Screen	Parameters	Preventive Measures	Recommended Visit Timing 1. m	6. m	12 . m	24. m
Organ	Complications & Test	Should be measured and evaluated recommended period at each office visit.	W.	2W.	M	3.M.
Respiratory	• Idiopathic pneumonia syndrome • Bronchiolitis obliterans syndrome • Cryptogenic organizing pneumonia • Sino-pulmonary infections 1. Pulmonary function test 2. Radiologic studies	✓ All HCT recipients				
		Routine clinical pulmonary evaluation	√	√	√	√
		Assessment of tobacco use and counselling against smoking	√	√	√	√
		PFT and focused radiologic assessment as clinically indicated for patients with symptoms or signs of lung compromise			√	√
		✓ Additional measures for special populations*		GVHD		
		Some experts recommend earlier and more frequent clinical evaluation and PFTs	√	√	√	√

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Organ	Complications & Test	Should be measured and evaluated recommended period at each office visit.	W.	2W.	M	3.M.
Cardiac and vascular	• Cardiomyopathy • Congestive heart failure • Arrhythmias • Coronary artery disease • Valvular anomaly • Cerebrovascular disease • Peripheral arterial disease ---------- 1. Cumulative anthracyclines dose 2. ECG & Echocardiogram in patients at risk and in symptomatic patients 3. Fasting blood sugar 4. Fasting lipid profile, HDL-C, LDL-C and triglycerides	✓ All HCT recipients				
		Routine clinical assessment of cardiovascular risk factors			√	√
		Education and counseling on “heart healthy” lifestyle (regular exercise, healthy weight, no smoking, dietary counselling) Visit uspreventiveservicestaskforce.org	√	√	√	√
		✓ Additional measures for special populations*			DM & HT	
		Early treatment of cardiovascular risk factors such as diabetes, hypertension and dyslipidemia	+	+	+	+

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Organ	Complications & Test	Should be measured and evaluated recommended period at each office visit.	W.	2W.	M	3.M.
Liver	• GVHD • Hepatitis B • Hepatitis C • Iron overload ---------- 1. Liver function test 2. PCR for hepatitis B or C 3. Liver biopsy 4. Serum ferritin 5. Imaging for iron overload	✓ All HCT recipients				
		LFTs; may be performed more frequently as clinically indicated	√	√	√	√
		✓ Additional measures for special populations*			Hepatitis	
		Monitor viral load by PCR for patients with known hepatitis B or C, with liver and infectious disease specialist consultation. Consider liver biopsy at 8-10 years after HCT to assess cirrhosis in patients with chronic HCV infection	+	+	+	+
		Serum ferritin for patients who have received RBC transfusions; consider liver biopsy or imaging study for abnormal results based on magnitude of elevation and clinical context; subsequent monitoring is suggested for patients with elevated LFTs, continued RBC transfusions, or presence of HCV infection	+	+	+	+

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Organ	Complications & Test	Should be measured and evaluated recommended period at each office visit.	W.	2W.	M	3M.
Renal and genitourinary	• Chronic kidney disease • Bladder dysfunction • Urinary tract infections • Genital GVHD ---------- 1. Urine protein 2. Serum creatinine 3. BUN 4. Pelvic (Genital) exam	✓ All HCT recipients				
		Blood pressure assessment with aggressive hypertension management	√	√	√	√
		Assess renal function with serum creatinine, BUN and urine protein. Further workup (kidney biopsy or renal ultrasound) for renal dysfunction as clinically indicated	√	√	√	√
		Avoid nephrotoxins and consider early referral to a nephrologist for evaluation and treatment in patients with progressive CKD	√	√	√	√
		Annual gynecologic exam in women			√	√
		✓ Additional measures for special populations*	GVHD &TBI			
		Consider more frequent gynecologic evaluation based on clinical symptoms		+	+	+

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Organ	Complications & Exam	Should be measured and evaluated recommended period at each office visit.	W.	2W.	M	3M.
Ocular	• Cataracts • Microvascular retinopathy • Sicca syndrome ---------- 1. Ophthalmologic exam	✓ All HCT recipients				
		Routine ocular clinical symptom evaluation; prompt ophthalmologic examination in patients with visual symptoms	√	√	√	√
		Ophthalmologic examination with measurement of visual acuity and fundus examination			√	+
		✓ Additional measures for special populations*	GVHD			
		Routine clinical evaluation, and if indicated, ophthalmologic examination more frequently	+	+	+	+

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Oral	• Sicca syndrome • Caries • Periodontal disease • Oral cancer ---------- 1. Dental assessment	✓ All HCT recipients				
		Clinical oral assessment with particular attention to intra-oral malignancy evaluation	√	√	√	√
		Check for history of xerostomia and high-risk habits and provide education about preventive oral health practices			√	√
		Dental assessment. Perform a thorough oral, head and neck and dental exam	√	√	√	√
		✓ Additional measures for special populations*	GVHD			
		Consider more frequent oral and dental assessments with particular attention to intra-oral malignancy evaluation	+	+	+	+

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Organ	Complications & Exam	Should be measured and evaluated recommended period at each office visit.	W.	2W.	M	3M.
Skin, Muscle, Connective tissue	• Cutaneous sclerosis • Myopathy • Fasciitis/scleroderma • Polymyositis ---------- 1. Skin exam 2. Evaluate ability to stand from a sitting position 3. Clinical evaluation of joint range of motion	✓ All HCT recipients				
		Counsel patients to perform routine self-exam of skin and avoid excessive exposure to sunlight without adequate protection	√	√	√	√
		Physical activity counseling. Follow general population guidelines for physical activity	√	√	√	√
		✓ Additional measures for special populations*	GVHD & Steroids			
		Frequent clinical evaluation for myopathy by manual muscle tests or by assessing ability to go from sitting to standing position	+	+	+	+
		Evaluate joint range of motion to detect sclerotic changes. Patients should also be instructed to perform self-assessment of range of motion	+	+	+	+
		Physical therapy consultation in patients with myopathy, fasciitis or scleroderma	+	+	+	+

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Organ	Complications & Exam	Should be measured and evaluated recommended period at each office visit.	W.	2W.	M	3M.
Endocrine Skeletal,ϕ	• Hypothyroidism • Hypoadrenalism • Hypogonadism • Growth retardation • Osteopenia/osteoporosis, ϕ • Avascular necrosis, ϕ ---------- 1. Thyroid function tests 2. FSH, LH, testosterone 3. Growth velocity in children 4. Dual photon densitometry, ϕ 5. MRI, ϕ	✓ All HCT recipients				
		Thyroid function tests — additional testing if relevant symptoms develop			√	√
		Clinical and endocrinologic gonadal assessment for post-pubertal women, subsequent follow-up based on menopausal status			√	+
		Gonadal function in men, including FSH, LH, and testosterone, should be assessed as warranted by symptoms			+	+
		Dual photon densitometry for adult women, and all allogeneic HCT recipients who are at high risk for bone loss (e.g., prolonged corticosteriod exposure); subsequent testing determined by defects or to assess response to therapy, ϕ			+	+
		✓ Additional measures for special populations*	GVHD & Steroids			
		Consider stress doses of corticosteroids during acute illness for patients who have received chronic corticosteroids	+	+	+	+
		Slow terminal tapering of corticosteroids for those with prolonged exposure	+	+	+	+
		Consider dual photon densitometry at an earlier date in patients with prolonged corticosteroid or calcineurin inhibitor exposure Steroids, ϕ	√	√	+	+

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Note: Refer growth age children to the pediatric endocrinology; assessment of thyroid, and growth hormone function if clinically indicated

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Organ	Complications & Exam	Should be measured and evaluated recommended period at each office visit.	W.	2W.	M	3M.
Second cancers	• Solid tumors • Hematologic malignancies • Post-transplant lymphoproliferative disorder (PTLD) --- 1. Mammogram 2. Screening for colon cancer (e.g., colonoscopy, 3. sigmoidoscopy, fecal occult blood testing) 4. Pap smear	✓ All HCT recipients				
		Counsel patients about risks of secondary malignancies and encourage them to perform self-exam (e.g., skin, testicles/genitalia) and counsel to avoid high-risk behaviors (e.g., smoking)			√	√
		Screen for second cancers — follow general population recommendations for cancer screening			√	√
		✓ Additional measures for special populations*	GVHD & TBI			
		Clinical and dental evaluation in patient suffering from GVHD with particular attention toward oral and pharyngeal cancer			+	+
		Screening mammography in women starting at age 25 or 8 years after radiation exposure, whichever occurs later but no later than age 40 Women with exposure to TBI/chest irradiation			+	+

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Organ	Complications & Exam	Should be measured and evaluated recommended period at each office visit.	W.	2W.	M	3M.
Nervous system and Psychosocial, ϕ sexuality, δ Fertilitiy, δ	• Leukoencephalopathy • Neuropsychological and cognitive deficits • Late infections • Calcineurin neurotoxicity • Peripheral neuropathy • Depression , ϕ • Anxiety , ϕ • Fatigue , ϕ • Sexual dysfunction , δ • Infertility, , δ ---------- 1. MRI 2. Neuropsychological testing 3. Psychological evaluation, ϕ 4. FSH, LH levels, δ	✓ All HCT recipients				
		Clinical evaluation for symptoms and signs of neurologic dysfunction. Diagnostic radiographs and nerve conduction studies for symptomatic patients		+	√	√
		Evaluate for changes in cognitive function, which may be subtle in adults			+	√
		Clinical assessment throughout recovery period, with mental health professional counseling recommended for those with recognized symptoms, ϕ	√	√	√	√
		Regularly assess level of spousal/caregiver psychological adjustment and family functioning. Encourage robust support networks, ϕ	√	√	√	√
		Consider referral to appropriate specialists for patients who are contemplating a pregnancy or are having difficulty conceiving, δ	√	√	√	√
		Query adults about sexual function, δ				
		✓ Additional measures for special populations*	Pediatric			
		Assessment for cognitive development milestones	+	+	+	+

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Part II: Vaccinations

Routine administration of vaccinations is vital for prevention of infectious complications in transplant recipients.

Transplant recipients may remain immunocompromised far beyond 2 years post-transplant, especially individuals with chronic GVHD. Therefore, patients should be routinely revaccinated after transplant until they regain immune competence.

This vaccination schedule[1] is based on international consensus guidelines[2,3] for preventing infectious complications among all transplant recipients and is recommended for both autologous and allogeneic HCT recipients.

1. Majhail NS, Rizzo JD, Lee SJ, et al. Recommended screening and preventive practices for long-term survivors after hematopoietic cell transplantation; Center for International Blood and Marrow Transplant Research (CIBMTR), American Society for Blood and Marrow Transplantation (ASBMT), European Group for Blood and Marrow Transplantation (EBMT), Asia-Pacific Blood and Marrow Transplantation Group (APBMT), Bone Marrow Transplant Society of Australia and New Zealand (BMTSANZ), East Mediterranean Blood and Marrow Transplantation Group (EMBMT) and Sociedade Brasileira de Transplante de Medula Ossea (SBTMO). Co-published in Biol Blood Marrow Transplant, 2012; 18(3): 348-371; Bone Marrow Transplant, 2012 47(3): 337–341; and Hematol Oncol Stem Cell Ther, 2012; 5(1): 1-30.
2. Tomblyn M, Chiller T, Einsele H, et al. Guidelines for preventing infectious complications among hematopoietic cell transplantation recipients: a global perspective. Biol Blood Marrow Transplant. 2009; 15: 1143-1238.
3. Ljungman P, Cordonnier C, Einsele H, et al. Vaccination of hematopoietic cell transplant recipients. Bone Marrow Transplant. 2009; 44: 521-526.

Use the chart:

- Become aware of the vaccinations transplant recipients need
- Plan for administration of vaccines

Part II: Vaccinations

Vaccine	Recommended for use after HCT	Time post-HCT to initiate vaccine	No. of doses [a]
Pneumococcal conjugate (PCV)	Yes	3-6 months	3-4 [b]
Tetanus, diphtheria, acellular pertussis [c]	Yes	6-12 months	3 [d]
Haemophilus influenzae conjugate	Yes	6-12 months	3
Meningococcal conjugate	Follow country recommendations for general population	6-12 months	1
Inactivated polio	Yes	6-12 months	3
Recombinant hepatitis B	Follow country recommendations for general population	6-12 months	3
Inactivated influenza	Yearly	4-6 months	1-2 [e]
Measles-mumps-rubella (live) [f,g]	Measles: All children and seronegative adults	24 months	1-2 [h]

See references on previous page for vaccinations considered optional or not recommended for HCT recipients and for vaccinations for family, close contacts and health care workers.

[a] A uniform specific interval between doses cannot be recommended, as various intervals have been used in studies. As a general guideline, a minimum of 1month between doses may be reasonable.

[b] Following the primary series of three PCV doses, a dose of the 23-valent polysaccharide pneumococcal vaccine (PPSV23) to broaden the immune response might be given. For patients with chronic GVHD who are likely to respond poorly to PPSV23, a fourth dose of the PCV should be considered instead of PPSV23.

[c] DTaP (diphtheria tetanus pertussis vaccine) is preferred, however, if only Tdap (tetanus toxoid-reduced diphtheria-toxoid reduced acellular pertussis vaccine) is available (for example, because DTaP is not licensed for adults), administer Tdap. Acellular pertussis vaccine is preferred, but the whole-cell pertussis vaccine should be used if it is the only pertussis vaccine available.

[d] See references on previous page for consideration of an additional dose(s) of Tdap for older children and adults.

[e] For children <9 years of age, two doses are recommended yearly between transplant and 9 years of age.

[f] Measles, mumps and rubella vaccines are usually given together as a combination vaccine. In females with pregnancy potential, vaccination with rubella vaccine either as a single or a combination vaccine is indicated.

[g] Not recommended <24 months post-HCT, in patients with active GVHD, and in patients on immune suppression.

[h] In children, two doses are favored.

Part III: Screening for chronic GVHD

Early detection of chronic graft-versus-host disease (GVHD) can help prevent irreversible organ damage and increase the quality of life of your transplant recipient.

Chronic GVHD, an immune response of the donor-derived T cells against recipient tissues, occurs in approximately 30–70% of patients receiving an allogeneic transplant.

This is a serious, potentially life-threatening post-transplant complication. Uncontrolled chronic GVHD is associated with increased non-relapse mortality, significant morbidity and lower health-related quality of life. However, with ongoing surveillance, judicious management and multidisciplinary care, most cases of chronic GVHD resolve within 5 years and the median duration of treatment is 2–3 years.

GVHD that is characterized by red rash, diarrhea, and elevated liver tests, and that usually starts before day 100, is called acute GVHD. When people develop GVHD symptoms in their mouth, eyes, skin or other organs, it is called chronic GVHD. When symptoms appear, the treatment recommendation is: ***Collaborate with the transplant center to confirm the diagnosis and develop a treatment plan.***

The following guidelines are based on published diagnostic criteria from the National Institutes of Health (NIH) Consensus Development Project on Chronic GVHD[1,2,3] (see references on page 22).

Part III: Screening for chronic GVHD

Use the following chart to:

- Identify clinical manifestations that are potential early indicators of chronic GVHD
- Trigger prompt clinical action if GVHD is suspected

If GVHD is suspected, it is recommended that you **collaborate with the patient's transplant center to confirm the diagnosis and to develop a treatment plan.** Your early detection and actions to manage chronic GVHD can help minimize permanent damage and improve the quality of life of your transplant recipient.

Important care principles

- *Early detection and definitive diagnosis are essential for successful treatment*
- *Definitive diagnosis of chronic GVHD requires excluding other diagnoses such as infection, drug effects, malignancies and residual post-inflammatory damage and scarring*
- *Involvement of a multidisciplinary team is essential*
- *Both topical and/or systemic treatment may be appropriate*
- *Infection prophylaxis and prompt and effective management of infections are crucial; infection is a leading cause of death in chronic GVHD*
- *Long-term follow-up is required to monitor for late sequelae*

Chronic GVHD Screening

Organ/Sites	Evaluation	Clinical Manifestation	Description of Clinical Manifestation	Photo
Skin	**Symptoms and signs** Itching, Dry skin, Rash, Sores Changes in skin coloring or texture Limited mobility Edema **Clinical examination** Complete visual examination of the skin with particular attention to pigmentary changes, rashes, textural changes, tightness, areas of thickening or skin breakdown, ulcers or erosions Palpation for areas of sclerosis or fasciitis **Diagnostic testing** Skin biopsy	**Poikiloderma**	Atrophic, pigmentary changes and telangiectasia	1
		Lichen planus-like features	Erythematous/violaceous flat-topped papules or plaques with or without surface reticulations or a silvery or shiny appearance	4, 5
		Sclerotic features	Smooth, waxy, indurated, thickened or tight skin and soft tissues caused by deep and diffuse sclerosis over a wide area	8, 9, 10
		Lichen sclerosus-like features	Discrete to coalescent, gray to white, moveable papules or plaques, often with follicular plugs, with a shiny appearance and wrinkled texture	6
		Morphea-like features	Localized patchy areas of moveable smooth or shiny skin with leather-like consistency, often with dyspigmentation	2
(Skin continued on next page)		**Depigmentation***	Loss of normal pigmentation (vitiligo)	8
		Papulosquamous lesions*	Scaly skin, with plaques and/or papules	

*Distinctive but insufficient alone to establish an unequivocal diagnosis of chronic GVHD without further testing or additional organ involvement.
**Rare, controversial, or non-specific features of chronic GVHD.
***Common in both acute and chronic GVHD.

Chronic GVHD Screening

Organ/Sites	Evaluation	Clinical Manifestation	Description of Clinical Manifestation	Photo
Skin (continued from previous page)	**Symptoms and signs** Itching Dry skin Limited mobility Rash Sores Changes in skin coloring or texture Edema **Clinical examination** Complete visual examination of the skin with particular attention to pigmentary changes, rashes, textural changes, tightness, areas of thickening or skin breakdown, ulcers or erosions Palpation for areas of sclerosis or fasciitis **Diagnostic testing** Skin biopsy	**Sweat impairment****	May manifest as heat intolerance due to loss of sweat glands	
		Ichthyosis**	Rough, thick and scaly skin	
		Hypopigmentation**	Diminished pigmentation of the skin	8
		Hyperpigmentation**	Darkening of the skin due to pigment deposition	4, 7, 8
		Keratosis pilaris**	Pale to erythematous perifollicular papules with spiny keratotic plugs within the follicular openings	3
		Maculopapular rash***	Raised and flat small, red lesions	12
		Erythema***	Abnormal redness of the skin	
		Pruritus***	Localized or generalized itching	
		Erosion3	Localized skin lesion characterized by complete or partial loss of only the epidermis	11
		Ulcer3	Localized skin lesion in which the whole of the epidermis and at least part of the dermis has been lost. May extend into the subcutaneous fat	

Chronic GVHD Screening

Organ/Sites	Evaluation	Clinical Manifestation	Description of Clinical Manifestation	Photo
Nails	**Symptoms and signs** Brittle nails Increased ridging in nails Splitting nails Nail loss **Clinical examination** Visual inspection of nails None	**Dystrophy***	Longitudinal ridging, splitting or brittleness	13
		Onycholysis*	Loosening of a nail from the nail bed beginning at the free edge and proceeding to the root	
		Nail loss*	Usually symmetric; affects most nails	
		Pterygium unguis*	Forward growth of the cuticle over the nail	
Scalp Body hair	**Diagnostic testing** Premature gray or thinning hair Itchy scalp Hair loss **Clinical examination** Visual inspection of scalp hair/body hair for changes in hair distribution, consistency and color **Diagnostic testing** None	**New onset of scarring or non-scarring scalp alopecia***	After initial recovery following chemotherapy or radiotherapy	14
		Loss of body hair*		
		Scaling*	An eruption composed of papules and scales	
		Thinning scalp hair**	Typically patchy, coarse or dull (not explained by endocrine or other causes)	
		Premature gray hair**		

*Distinctive but insufficient alone to establish an unequivocal diagnosis of chronic GVHD without further testing or additional organ involvement.
**Rare, controversial, or non-specific features of chronic GVHD.
***Common in both acute and chronic GVHD.
[3] See references on page 22.

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Chronic GVHD Screening

Organ/Sites	Evaluation	Clinical Manifestation	Description of Clinical Manifestation	Photo
Eyes	**Symptoms and signs** Dry, burning, gritty eyes Itching Orbital pain Difficulty opening eyes in the morning Sensitivity to light and wind Excessive tearing Diminished visual acuity and/or blurring **Clinical examination** Visual inspection of the conjunctivae and sclerae Ophthalmologic exam **Diagnostic testing** Schirmer's tear test Slit-lamp examination	**New onset dry, gritty or painful eyes***	New ocular sicca documented by low Schirmer's test values with a mean value of both eyes ≤5 mm of wetting at 5 minutes, but note that Schirmer's test values are not useful for follow-up of ocular GVHD due to poor correlation with symptom change	
		Cicatricial conjunctivitis*	Fibrous tissue scaring and inflammation	
		Keratoconjunctivitis sicca (KCS)*	Inflammation of cornea and conjunctivae, with dryness, grittiness and/or orbital pain. Slit lamp exam with mean Schirmer's test values of 6 to 10 mm, not due to other causes	22, 23
		Confluent areas of punctate keratopathy*	Closely spaced, non-inflamed pinpoint de- fects indicating loss of corneal epithelium, and observed with fluorescein staining	
		Photophobia**	Increased sensitivity to light	
		Periorbital hyperpigmentation**	Excess pigmentation in the tissues surrounding or lining the orbit of the eye	
		Blepharitis**	Erythema and edema of the eyelids and telangiectasia of lid margin	24

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Chronic GVHD Screening

Organ	Evaluation	Clinical Manifestation	Description of Clinical Manifestation	Photo
Mouth	**Symptoms and signs** Dryness Chapped lips Ulcers Swelling, redness, pain and/or bleeding of gums Sensitivity to spicy foods, toothpaste or soda pop Pain **Clinical examination** Visual inspection of the entire mouth **Diagnostic testing** Oral biopsy	**Lichen planus-like changes**	Hyperkeratotic white lines and lacy-appearing lesions on the buccal mucosa and tongue, palate or lips	16
		Xerostomia*	Abnormal dryness of the mouth	
		Mucoceles*	Vesicle-like or raised masses due to minor salivary gland inflammation and damage	17
		Mucosal atrophy*	Thinning of mucosal tissue	19
		Pseudomembranes*	Loosely adherent fibrinous exudate on the surface of a mucous membrane	20
		Ulcers*	Open sore inside mouth caused by a break in mucous membrane or epithelium on lips or surrounding mouth	20, 21
		Erythema***	Severity of erythema or "redness" can vary from mild to severe	17, 18, 19, 20
		Gingivitis***	Mucosal fiber damage causes smooth/ inflamed gingival surface, in contrast to the dimpled or stippled appearance of normal gingivae. Entire width of the attached gingivae will be erythematous	
		Mucositis***	Inflammation of mucous membrane	

*Distinctive but insufficient alone to establish an unequivocal diagnosis of chronic GVHD without further testing or additional organ involvement.
**Rare, controversial, or non-specific features of chronic GVHD.
***Common in both acute and chronic GVHD. Pain**

Chronic GVHD Screening

Organ	Evaluation	Clinical Manifestation	Description of Clinical Manifestation	Photo
Muscles, fascia, joints	**Symptoms and signs** Muscle cramps Muscle pain Muscle weakness Joint stiffness Restricted range of motion Tightened muscles, tendons and fascia Contractures **Clinical examination** Palpation for areas of thickening, tightening, shortening of muscles or fascia; muscle tenderness Evaluate range of motion Muscle strength testing Inspection for signs of edema or peau d'orange skin changes Visual inspection for grooving, ridging **Diagnostic testing** Creatinine kinase Aldolase Electromyography	**Fasciitis**	Stiffness, restricted range of motion	9
		Joint stiffness or contractures (secondary to fasciitis or sclerosis)	Groove sign, dimpling	
		Myositis or polymyositis*	Muscle tenderness and elevated muscle enzymes. Evaluate with electromyography and measurement of creatinine phosphokinase and aldolase. Muscle/sural nerve biopsies should be considered in the absence of other manifestations of GVHD to rule out other causes of myositis	
		Edema**	Present in extremities, with or without erythema and peau d'orange skin	15
		Muscle cramps**	May be present with increased muscle enzymes	
		Arthralgia or arthritis**	Uncommon, occasionally associated with the presence of autoantibodies	

*Distinctive but insufficient alone to establish an unequivocal diagnosis of chronic GVHD without further testing or additional organ involvement.
**Rare, controversial, or non-specific features of chronic GVHD.
***Common in both acute and chronic GVHD.

Chronic GVHD Screening

Organ	Evaluation	Clinical Manifestation	Description of Clinical Manifestation	Photo
GI tract	**Symptoms and signs** Anorexia Nausea Vomiting Abdominal pain Diarrhea, Bloating Cramping Weight loss Painful swallowing Difficulty swallowing dry foods/pills **Clinical examination** Examination of mouth and hypopharynx **Diagnostic testing** Endoscopy Barium contrast radiograph Swallowing study Stool test for fecal fat Biopsy Amylase Lipase	**Esophageal web**	Smooth, circumferential ring of squamous mucosa; documented by endoscopy or barium contrast radiograph	
		Upper esophageal strictures or stenosis	Narrowing of the upper to mid third of the esophagus; documented by endoscopy or barium contrast radiograph	
		Pancreatic exocrine insufficiency**	Pancreatic atrophy and exocrine insufficiency leading to inability to properly digest food due to a lack of digestive enzymes; often improves with enzyme supplementation	
		Anorexia* Nausea*** Vomiting*** Diarrhea*** Weight loss*** Failure to thrive (infants and children)***		

Chronic GVHD Screening

Organ	Evaluation	Clinical Manifestation	Description of Clinical Manifestation	Photo
Lungs	**Symptoms and signs** Difficulty breathing Wheezing Shortness of breath at rest and/or with exertion Dry cough **Clinical examination** Chest ausculation Pulse oximetry **Diagnostic testing** Pulmonary function testing (PFT) Expiratory CT Lung biopsy	**Bronchiolitis obliterans diagnosed using PFT**	Obstructive lung defect. May include dyspenea on exertion, cough, or wheezing	
		Air trapping and bronchiectasis on chest CT*	Evidence of air trapping on expiratory CT, small airway thickening	
		Cryptogenic organizing pneumonia**	Inflammation of the bronchioles and surrounding tissue in the lungs	

Chronic GVHD Screening

Organ	Evaluation	Clinical Manifestation	Description of Clinical Manifestation	Photo
Liver	**Symptoms and signs** Jaundice Malaise Itching Fatigue **Clinical examination** Assess for hepatomegaly and right upper quadrant abdominal tenderness **Diagnostic testing** Total and direct bilirubin Alkaline phosphatase ALT: Alanine aminotransferase AST: Aspartate aminotransferase GGT: Gamma glutamyl transpeptidase 5'-NT: 5' Nucleotidase Liver biopsy may be needed in the absence of GVHD in another organ	**Hepatitis*** **	Rise in serum alanine aminotransferase, > 2x upper limit of normal, with or without jaundice	
		Progressive cholestatic features* **	The flow of bile from the liver is blocked; total bilirubin, alkaline phosphatase > 2x upper limit of normal; elevated gamma-glutamyl transpeptidase, followed by jaundice	

*Distinctive but insufficient alone to establish an unequivocal diagnosis of chronic GVHD without further testing or additional organ involvement.
**Rare, controversial, or non-specific features of chronic GVHD.
***Common in both acute and chronic GVHD.

Chronic GVHD Screening

Organ	Evaluation	Clinical Manifestation	Description of Clinical Manifestation	Photo
Genitalia	**Symptoms and signs** Itching Painful intercourse Dryness Painful urination Burning **Clinical examination** Visual inspection of genitalia Pelvic exam **Diagnostic testing** Biopsy	**Lichen planus-like features**	Erythematous/violaceous tissue changes	
		Lichen sclerosus-like features	White, atrophic papules that may coalesce into plaques	
		Females: Vaginal scarring or clitoral/ labial agglutination	A narrowing of the vagina, often with accompanying tissue changes such as dryness, loss of elasticity and resilience, adhesion and scar tissue	
		Males: Phimosis or urethral/ meatus scarring or stenosis		
		Fissures*	A break or slit in tissue typically appearing at the junction of skin and mucous membrane	
		Erosions*	Localized destruction or loss of the epidermis	
		Ulcers*	Localized destruction or loss below the epidermis	

Chronic GVHD Screening

Organ	Evaluation	Clinical Manifestation	Description of Clinical Manifestation	Photo
Hematopoietic immune	**Symptoms and signs** None **Clinical examination** None **Diagnostic testing** Complete blood count CBC differential Test for presence of autoantibodies Quantitative immunoglobulin levels For these manifestations, chronic GVHD is often a diagnosis of exclusion	**Thrombocytopenia****	Persistent decrease in the number of blood platelets; ☛: <100,000/μL	
		Eosinophilia**	Abnormal increase in the number of eosinophils; ☛: >500/μL	
		Lymphopenia**	Reduction in the number of lymphocytes; ☛: <500/μL	
		Hypo- or hyper-gammaglobulinemia**	Deficiency or excess of gamma globulins in the peripheral blood	
		Autoantibodies** • Autoimmune hemolytic anemia • Idiopathic thrombocytopenic purpura	Autoantibodies may develop, including antinuclear antibody, anti-centromere antibody, anti-mitochondrial antibody, anti-ENA screen, anti-double stranded DNA antibody, anticardiolipin antibody	
		Raynaud's phenomenon**	Disruption of blood flow to digits and skin	

Chronic GVHD Screening

Organ	Evaluation	Clinical Manifestation	Description of Clinical Manifestation	Photo
Other	Distinctive but insufficient alone to establish an unequivocal diagnosis of chronic GVHD without further testing or additional organ involvement.	**Pericardial or pleural effusions** **Ascites**** **Peripheral neuropathy**** **Nephrotic syndrome**** **Myasthenia gravis**** **Cardiac conduction abnormality or cardiomyopathy****	• Although these manifestations cannot be used to establish a diagnosis of chronic GVHD, a wide range of organ system • manifestations including neurologic complications, nephrotic syndrome and cardiac abnormalities have been described in assocation with cGVHD and may represent cGVHD manifestations. If after careful differential diagnosis no alternative etiologic factor is identified, it may be concluded that these manifestations represent chronic GVHD disease activity.	

Appendix-I

✓ Initial CMV Monitoring:

*CMV + recipients of allogeneic transplants should have monitored in blood weekly until day 100.

* CMV CD34 selected autologous transplants should have monitored weekly until day 100.

*CMV + ive cord blood recipients should have monitored twice weekly until day 100.

*CMV - ive recipients of cord blood should have monitored weekly until day 100.

*CMV - ive / + ive non-cord blood allogeneic recipients should be monitored weekly until day 60.

*CMV - ive unmodified autologous recipients should be monitored weekly until day 60

✓ +100 posttransplant, CMV monitoring:

CMV blood testing should be continued, initially weekly, until 1 year after transplant for allogeneic recipients at risk of late CMV disease which include:

*Patients treated for CMV viremia in the first 100 days after transplantation

* Cord blood transplant recipients who were CMV seropositive

* Patients who received Letermovir prophylaxis beyond day +60 after transplant

* Patients who received Anti-Human Thymocyte Globulin in conditioning or for GVHD

* Patients treated with > .05 mg/kg/day prednisone or equivalent other agents for GVHD

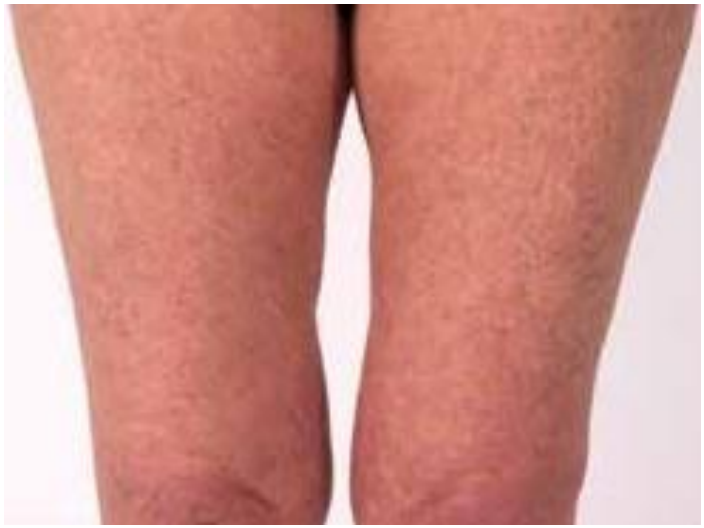
* (Non-Cord Blood patients every other week surveillance if on < 0.5 mg/kg/day prednisone.)

***Transplant recipients who received ATG as part of transplant conditioning and the patients receiving ATG for the treatment of steroids refractory GVHD** : Weekly blood monitoring by PCR for EBV, adenovirus, and CMV is recommended for at least 6 months after last dose of ATG or absolute lymphocyte count >300 cells/mm3, or CD4 count > 200 cells per microliter whichever is later for recipients at increased risk for viral disease which include:

*Surveillance may be **stopped** entirely after 2 additional negative tests if tapering of immunosuppression continues and **Resume** weekly CMV surveillance testing if treatment with immunosuppression is increased or re-initiated for GVHD.

Chronic GVHD Photo Atlas

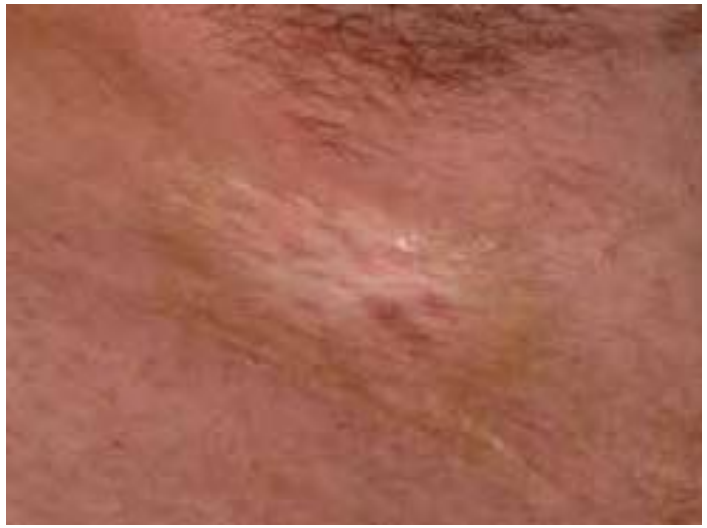
This photo atlas contains pictorial representations of various clinical manifestations of chronic GVHD. Refer to the information in the preceding chart for a full description of all manifestations.



1. Poikiloderma

Hypo- and hyper-pigmentary changes with erythema and atrophy.

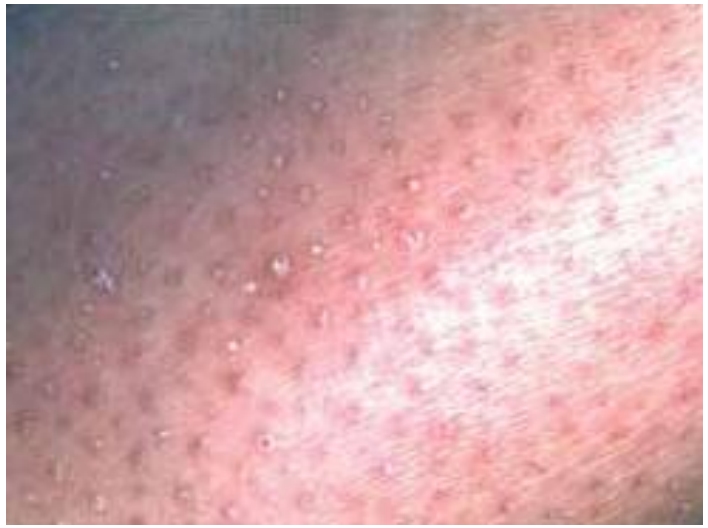
See Chart page 3



2. Morphea-like

Localized patchy area(s) of moveable smooth or shiny skin with a leather-like waxy or hardened consistency. Note the fibrotic, hypopigmented area in the center of the plaque with a slightly hyperpigmented border.

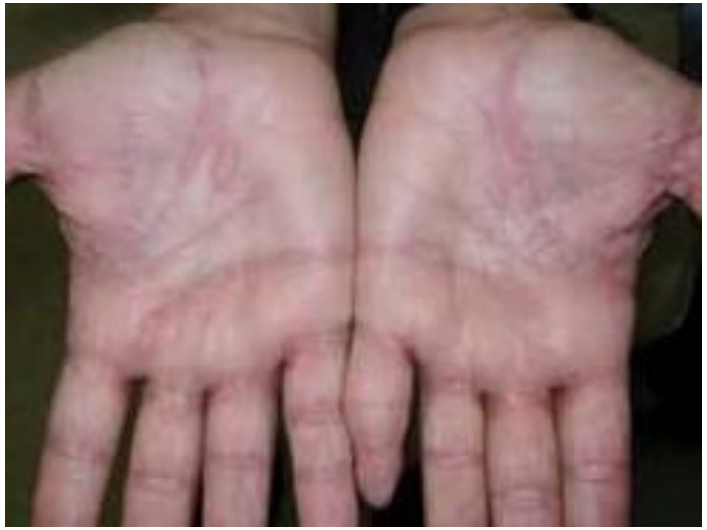
See Chart page 3



3. Keratosis pilaris

Skin-colored to erythematous perifollicular papules with spiny keratotic plugs within the follicular openings.

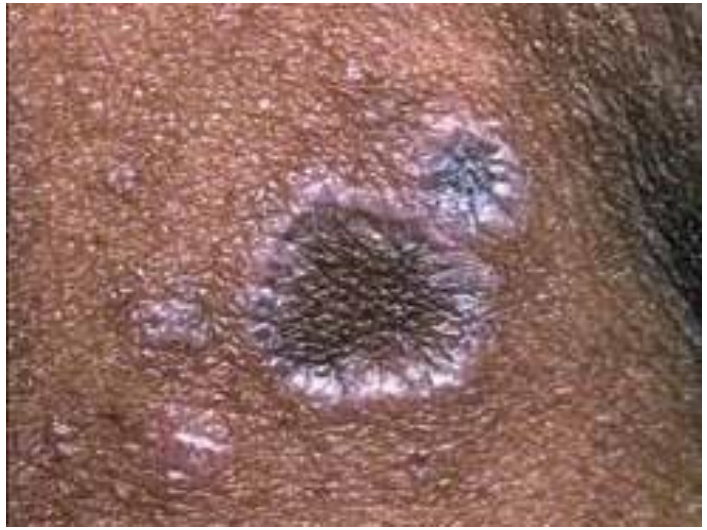
See Chart page 4



4. Lichen planus-like

Hyperpigmented/purple papules which may coalesce into annular (ring-like) small plaques. These lesions closely resemble the dermatologic disease lichen planus.

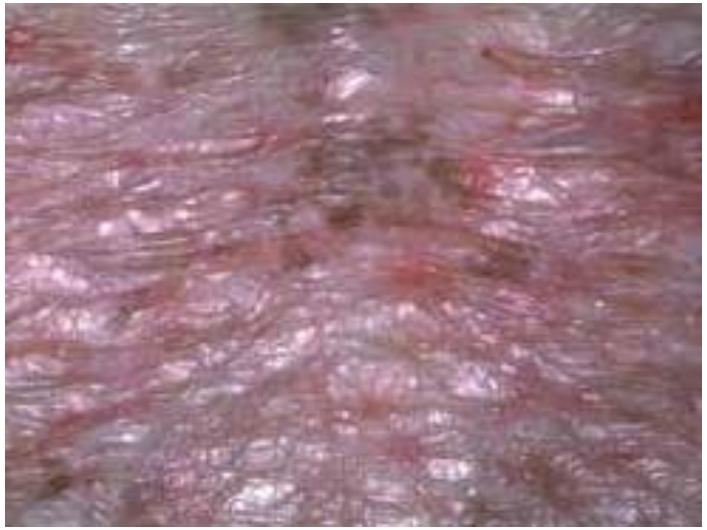
See Chart page 3, 4



5. Lichen planus-like

Discrete to coalescent gray to white moveable papules or plaques.

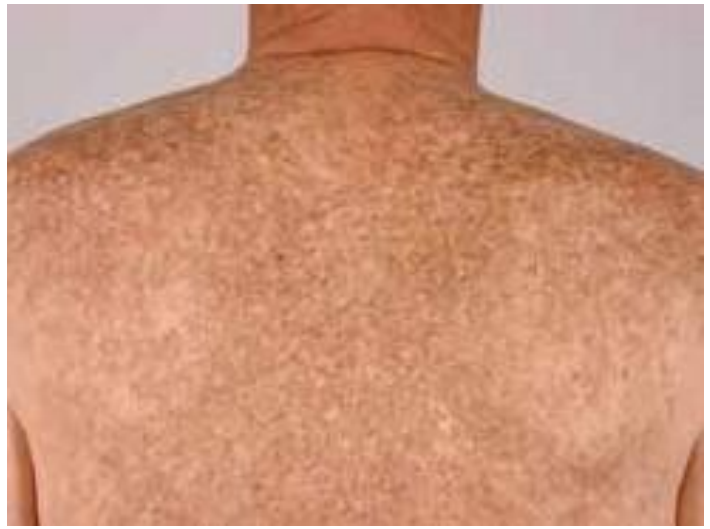
See Chart page 3



6. Lichen sclerosus-like

Close-up showing wrinkled texture and shiny appearance. Lesions tend to be grouped in discrete patches.

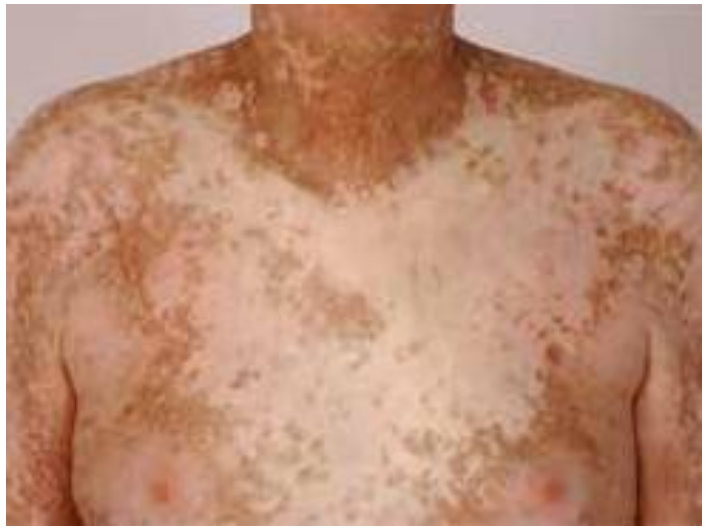
See Chart page 3



7. Hyperpigmentation

Excess pigmentation in the skin; may manifest in a widespread reticulated pattern.

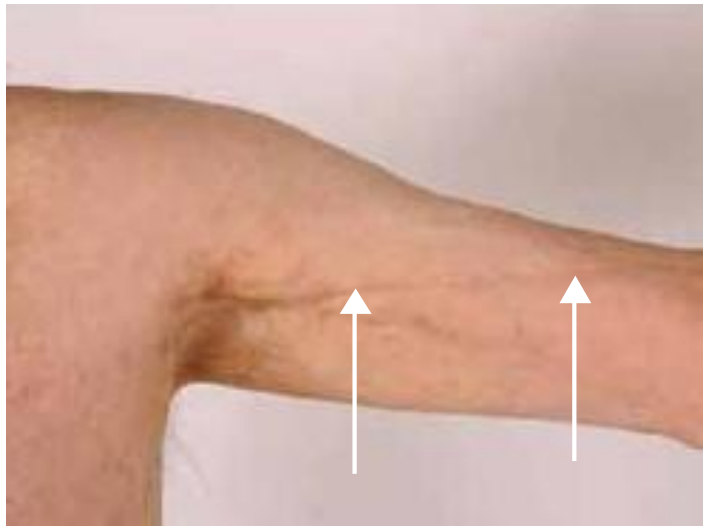
See Chart page 4



8. Hypopigmentation, hyperpigmentation, depigmentation, sclerosis

Diminished (hypo-) or excess (hyper-) pigmentation in the skin. Sclerotic tissue is hard and fibrous, with a decreased ability to pinch. Superficial sclerosis is moveable upon palpation, while deep sclerosis is hidebound and fixed.

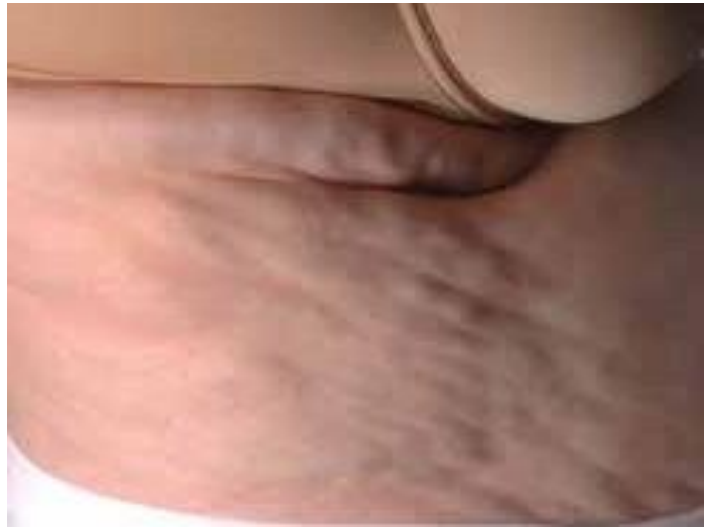
See Chart page 3, 4



9. Sclerosis, fasciitis

Subcutaneous sclerosis/fasciitis can be detected by a "groove sign" seen here.

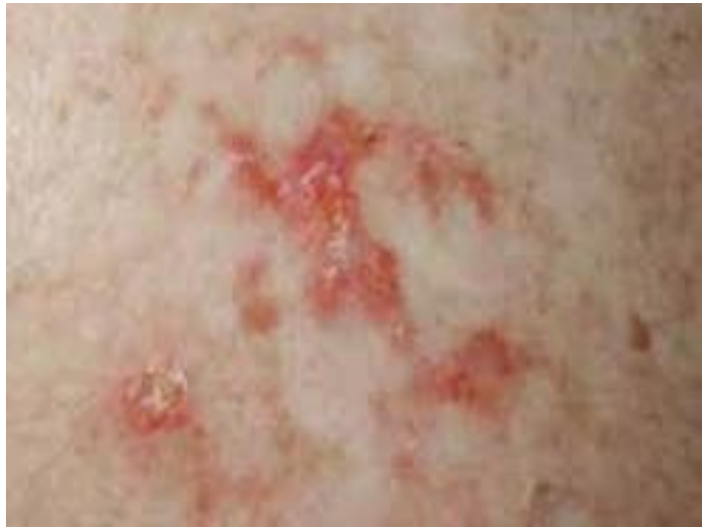
See Chart page 3, 9



10. Sclerosis

Subcutaneous sclerosis can be manifested by rippling, dimpling of the skin and a resultant cellulite-like appearance.

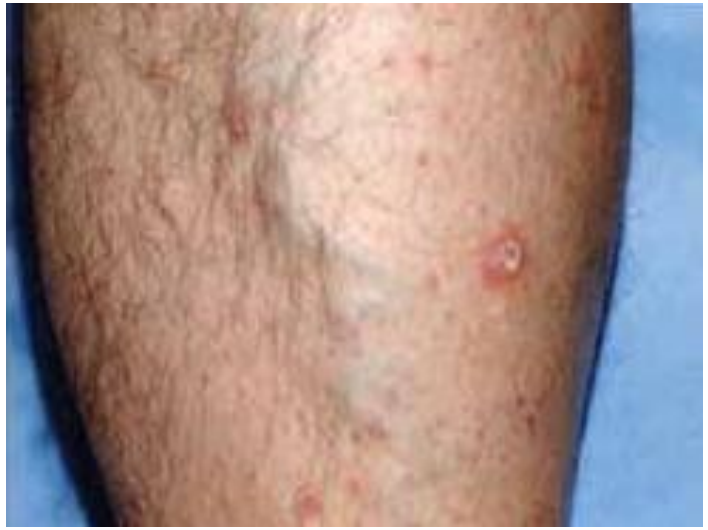
See Chart page 3



11. Erosion

Localized tissue destruction characterized by complete or partial loss of only the epidermis.

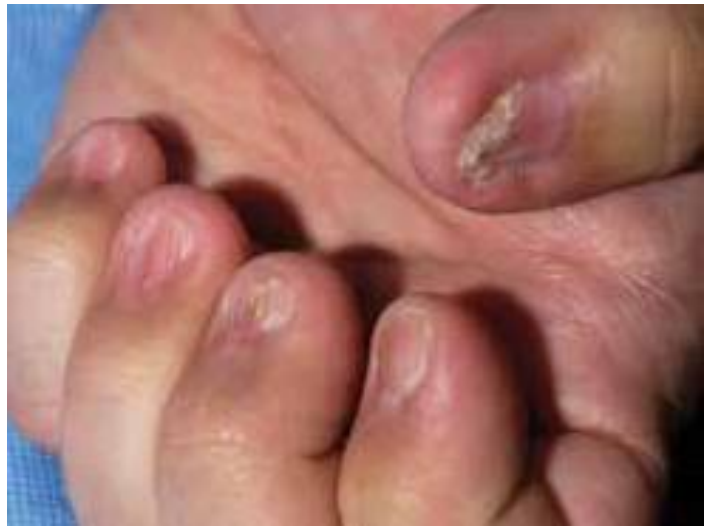
See Chart page 4



12. Maculopapular

Raised and flat small, red lesions.

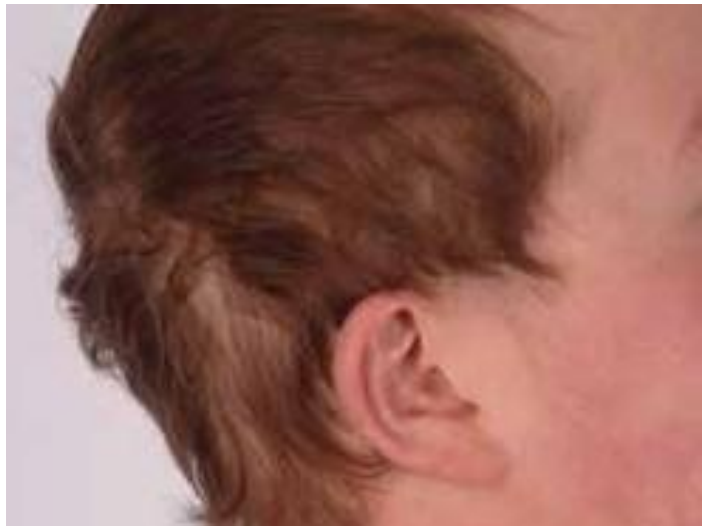
See Chart page 4



13. Nail dystrophy

Longitudinal ridging, splitting, or brittle features of nails. Note periungual erythema.

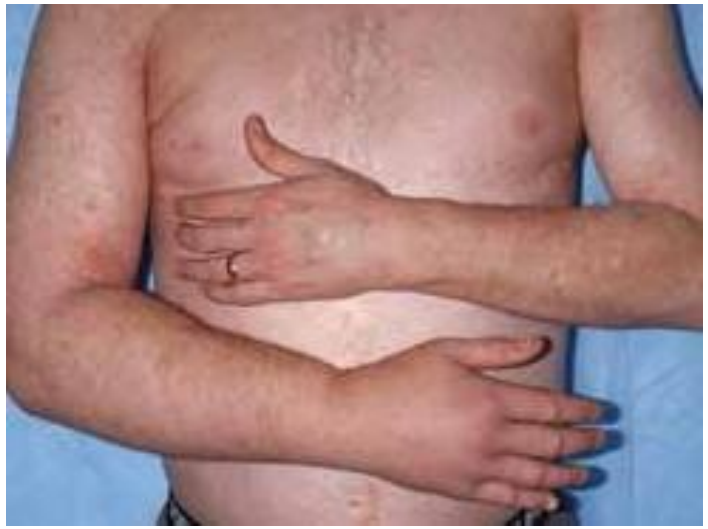
See Chart page 5



14. Alopecia

Patchy alopecia is shown. May also include loss of body hair (after initial recovery of hair growth following chemotherapy or radiotherapy).

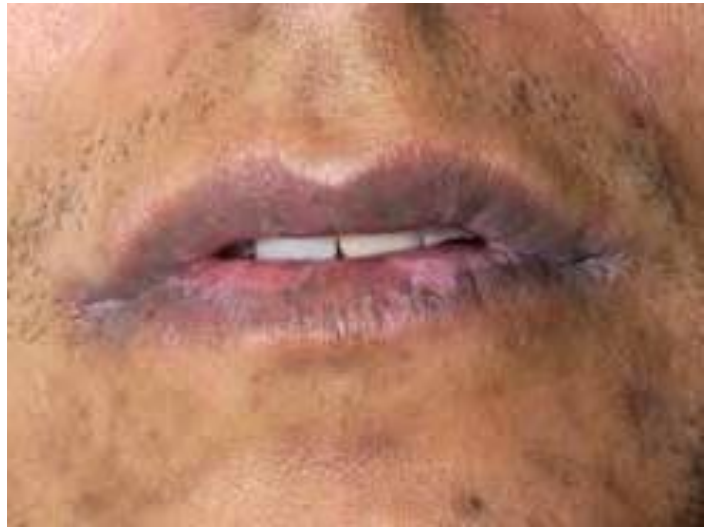
See Chart page 5



15. Edema

Edema in the extremities can be bilateral or unilateral (shown). May be present with erythema and peau d'orange skin. Edema may be associated as prodromal symptom to subcutaneous sclerosis and fasciitis.

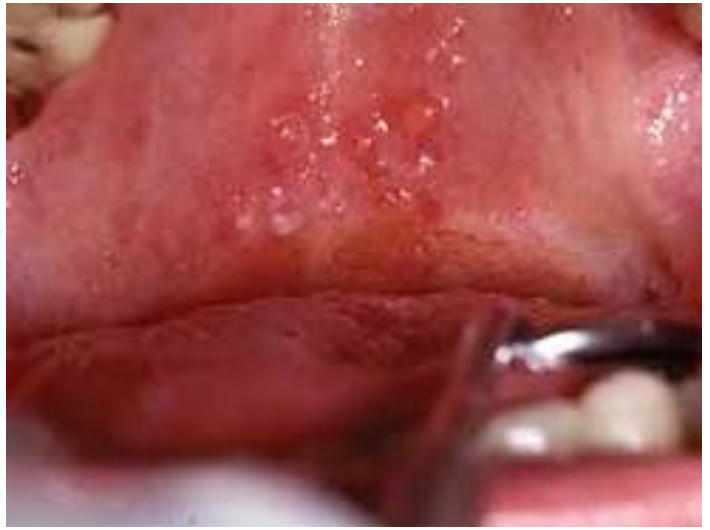
See Chart page 9



16. Lichen planus

Lichenoid changes extending from the labial mucosa to the lip. Cheilosis (surface scaling and fissures in the corners of the mouth) is also present.

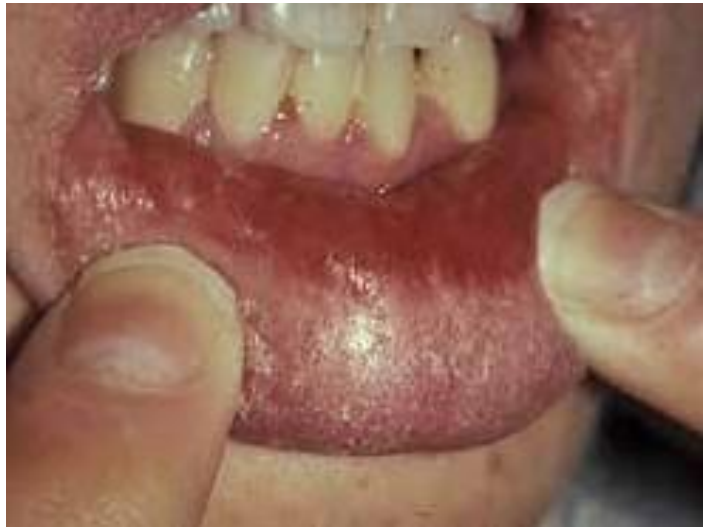
See Chart page 7



17. Mucoceles

Numerous vesicle-like mucoceles are seen along the center of the soft palate. Patchy white lichenoid hyperkeratosis and interspersed moderate erythematous changes are also evident across soft palate.

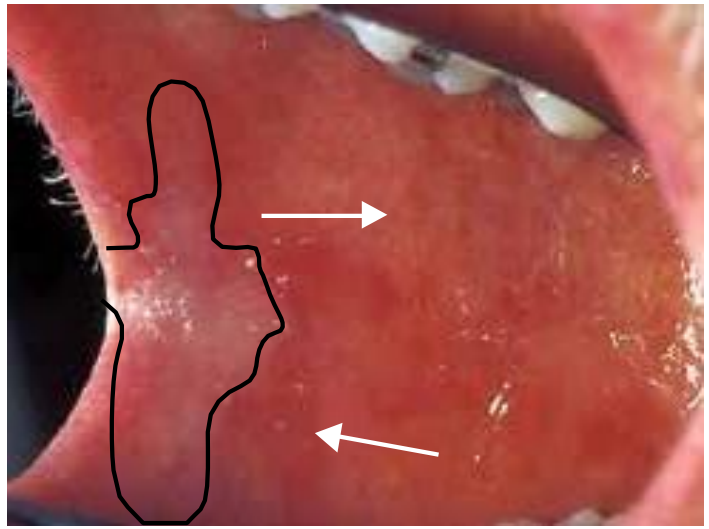
See Chart page 7



18. Erythema

Chapping and erythema of the vermillion lip. Erythema of labial mucosa.

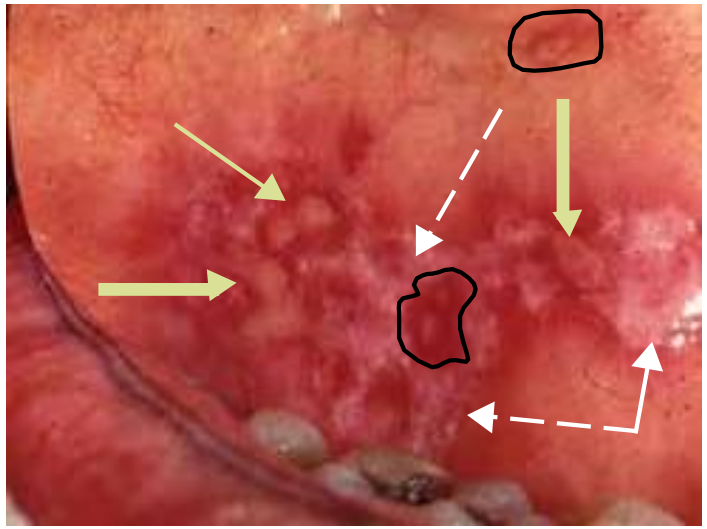
See Chart page 7



19. Erythema, hyperkeratinization

Patchy erythema (arrows) and sheet-like hyperkeratinization (black outline). Also note atrophy of buccal mucosal tissues.

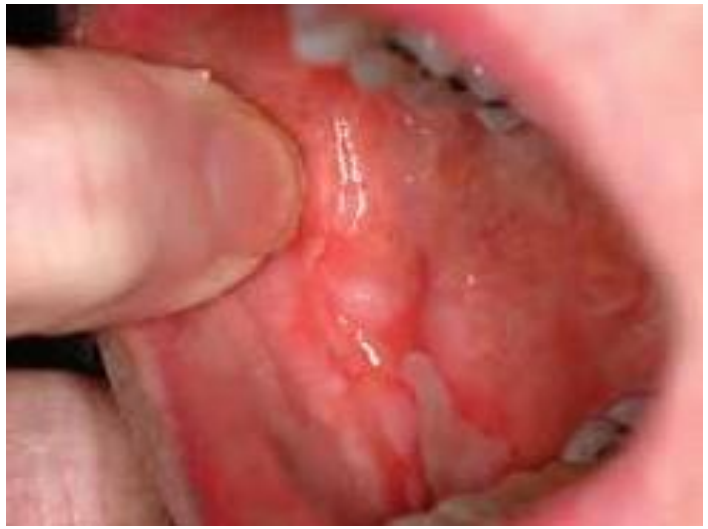
See Chart page 7



20. Erythema, ulcerations, hyperkeratinization

Mixed pseudomembranous fibrin exudate (light green arrows). Lichenoid hyperkeratotic changes (white arrows) involving the buccal mucosa. Erythema (black outline) surrounding pseudomembranous ulcerations.

See Chart page 7



21. Ulcerations

White patchy pseudomembranous ulcerations.

See Chart page 7

22. Keratoconjunctivitis sicca

Inadequate tear production (measured by Schirmer's test) and conjunctival erythema. Also note scleral injection and chemosis (conjuctival edema).

See Chart page 6

23. Keratoconjunctivitis sicca

Note scleral injection and conjunctival erythema.

See Chart page 6

24. Blepharitis

Thickened, edematous and erythematous eyelid margins. Also note plugging of meibomian gland orifices (along the eyelid margin) and significant conjunctival hyperemia/injection.

See Chart page 6

Photo credits:

Photos 3, 4, 8, 9, 11,12: Maria L. Turner, M.D.; Edward W. Cowen, M.D.; Dermatology Branch, National Cancer Institute, NIH, Bethesda, Md. Photos 1,2, 5-7, 10, 13-15: Edward W. Cowen, M.D.; Dermatology Branch, National Cancer Institute, NIH, Bethesda, Md.
Photos 16-21: Mark M. Schubert, D.D.S., M.S.D.; Fred Hutchinson Cancer Research Center, Seattle, Wash. Photo 22: Mary E.D. Flowers, M.D.; University of Washington, Seattle, Wash.
Photo 24: Janine A. Smith, M.D.; National Eye Institute, NIH, Bethesda, Md. All photos used with permission.

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[3]These guidelines have been developed by the National Marrow Donor Program® (NMDP)/Be The Match® in consultation with Sandra A. Mitchell, CRNP, MScN, AOCN; National Institutes of Health Clinical Center; and Steven Z. Pavletic, M.D.; National Cancer Institute, National Institutes of Health, Bethesda, Md. The information in this document does not represent the official position of the NIH or the U.S. Government.

Additional review from:

Dennis L. Confer, M.D., NMDP/Be The Match, Minneapolis, Minn. Linda J. Burns, M.D., NMDP/Be The Match, Minneapolis, Minn.
Madan Jagasia, M.D., Vanderbilt University Medical Center, Nashville, Tenn. Stephanie J. Lee, M.D., Fred Hutchinson Cancer Research Center, Seattle, Wash.