



Prior Authorization Criteria Updates Effective May 1, 2022

UCare Individual & Family Plans UCare Individual & Family Plans with M Health Fairview

On May 1, 2022, prior authorization criteria for the drugs listed below will be updated. These changes will be reflected in the [2022 Prior Authorization Criteria](#) document.

Benlysta	
PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	Concurrent use with other biologics or Lupkynis (voclosporin capsules). Rheumatoid Arthritis.
Required Medical Information	Diagnosis, lab results, other therapies tried
Age Restrictions	Subcutaneous - 18 years or older, IV - 5 years or older
Prescriber Restrictions	LN - Prescribed by or in consultation with a nephrologist or rheumatologist. SLE - Prescribed by or in consultation with a rheumatologist, clinical immunologist, nephrologist, neurologist, or dermatologist.
Coverage Duration	LN initial - 6 mo. SLE initial - 4 mo. Continuation - 1 year.
Other Criteria	Lupus Nephritis (LN) - Approve if pt has autoantibody-positive SLE, defined as positive for antinuclear antibodies (ANA) and/or anti-double-stranded DNA (anti-dsDNA) antibody and the medication is being used concurrently with at least one other standard therapy, unless intolerant as determined by the prescriber. Continuation - Approve if pt has responded to Benlysta and the medication is being used concurrently with at least one other standard therapy, unless intolerant, as determined by the prescriber. Systemic Lupus Erythematosus (SLE) - Approve if pt has autoantibody-positive SLE, defined as positive for antinuclear antibodies (ANA) and/or anti-double-stranded DNA (anti-dsDNA) antibody and the medication is being used concurrently with at least one other standard therapy, unless intolerant as determined by the prescriber. Continuation - Approve if pt has responded to Benlysta and the medication is being used concurrently with at least one other standard therapy, unless intolerant, as determined by the prescriber.

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Dupixent	
PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	Concurrent use with another anti-interleukin monoclonal antibody (e.g. Cinqair, Nucala, Fasenra). Concurrent use with Xolair. Eosinophilic Esophagitis.
Required Medical Information	Diagnosis, prescriber specialty, other medications tried and length of trials.
Age Restrictions	Asthma - 6 years or older. Atopic Dermatitis - 6 years or older. Nasal Polyps - 18 years or older.
Prescriber Restrictions	Atopic Dermatitis - Prescribed by or in consultation with an allergist, immunologist or dermatologist. Asthma - prescribed by or in consultation with an allergist, immunologist or pulmonologist. Nasal Polyps - prescribed by or in consultation with an allergist, immunologist or otolaryngologist.
Coverage Duration	AD: Initial - 4 mo. Cont - 1 year. Asthma/Nasal Polyps: Initial - 6 mo. Cont - 1 year.
Other Criteria	Asthma, Initial - Approve if pt meets the following criteria (i, ii, and iii): i. Pt has a blood eosinophil level of greater than or equal to 150 cells per microliter within the previous 6 weeks or within 6 weeks prior to treatment with any anti-interleukin (IL) therapy or Xolair OR has oral corticosteroid-dependent asthma AND ii. Pt has received combination therapy with both an inhaled corticosteroid (ICS) and at least one additional asthma controller/maintenance medication for at least 3 consecutive months AND iii. Pt's asthma is uncontrolled or was uncontrolled prior to starting any anti-IL therapy as defined by one of the following (a, b, c, d or e): a) experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year OR b) experienced one or more asthma exacerbation requiring hospitalization or an Emergency Department visit in the previous year OR c) has a forced expiratory volume in 1 second (FEV1) less than 80% predicted OR d) has an FEV1/forced vital capacity (FVC) less than 0.80 OR e) The pt's asthma worsens upon tapering of oral corticosteroid therapy. Continuation - Approve if pt continues to receive therapy with an inhaled corticosteroid and has recieved at least 6 months of Dupixent and has responded to therapy as determined by the prescriber. Atopic Dermatitis, Initial - Pt has has atopic dermatitis involvement

	<p>estimated to be greater than 10% of the body surface area (BSA), and has tried a medium-potency or stronger topical corticosteroid for at least 28 days with inadequate efficacy, according to the prescriber OR Pt has atopic dermatitis involvement estimated to be less than 10% of the BSA, affecting only the face, eyes/eyelids, skin folds, and/or genitalia, and has tried tacrolimus for at least 28 days with inadequate efficacy, according to the prescriber. Continuation - Approve if the pt has received at least 4 months of Dupixent and has responded to therapy as determined by the prescriber.</p> <p>Nasal Polyps - Pt has chronic rhinosinusitis with nasal polyposis as evidenced by direct examination, endoscopy, or sinus computed tomography (CT) scan, has been using an intranasal corticosteroid for 3 months and will continue to use in combination with Dupixent, and has experiencing two or more of the following for at least 6 months: nasal congestion, nasal obstruction, nasal discharge, and/or reduction/loss of smell AND either has received treatment with a systemic corticosteroid within the previous 2 years (unless contraindicated) or has had prior surgery for nasal polyps. Continuation - Approve if pt continues to receive therapy with an intranasal corticosteroid and has received at least 6 months of Dupixent and has responded to therapy as determined by the prescriber.</p>
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Evrysdi	
PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded
Exclusion Criteria	Patient has Complete Paralysis of All Limbs. Patient has Permanent Ventilator Dependence. Patient is less than 2 months of age.
Required Medical Information	Diagnosis, SMA exam results, genetic testing results, pregnancy status, weight
Age Restrictions	Initial - 2 months up to 25 years of age. Continuation - pt was less than 25 years when Evrysdi was started
Prescriber Restrictions	Prescribed by or in consultation with a physician who specializes in the management of patients with spinal muscular atrophy and/or neuromuscular disorders
Coverage Duration	4 months
Other Criteria	Spinal Muscular Atrophy (SMA) - Approve if baseline motor ability assessment that suggests spinal muscular atrophy (based on age, motor ability, and development) is provided from one of the following exams [documentation required]: Bayley Scales of Infant and Toddler Development, Third Edition (BSID-III) [Item 22], Children's Hospital

	<p>of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND), Hammersmith Functional Motor Scale Expanded (HFMSE), Hammersmith Infant Neurological Exam Part 2 (HINE-2), Motor Function Measure-32 Items (MFM-32), Revised Upper Limb Module (RULM) test, or World Health Organization motor milestone scale AND pt has had a genetic test confirming the diagnosis of SMA with bi-allelic mutations in the survival motor neuron 1 (SMN1) gene reported as at least one of the following: homozygous deletion, homozygous mutation, or compound heterozygous mutation [documentation required] AND has two to four survival motor neuron 2 (SMN2) gene copies [documentation required] AND according to the prescriber, the patient has objective signs consistent with spinal muscular atrophy Types 1, 2, or 3 [documentation required] AND for pts currently receiving or who have received prior treatment with Spinraza, the prescriber attests that further therapy with Spinraza will be discontinued AND pt has not received Zolgensma in the past AND females of current reproductive potential must have the prescriber confirm BOTH of the following: pt is not currently pregnant and effective contraception will be utilized during treatment and for 1 month after the last Evrysdi dose AND dosing of Evrysdi meets ONE of the following based on the current (within the past 1 month) kg weight (a, b, or c): a) 0.2 mg/kg once daily if the patient is 2 months to less than 2 years of age OR b) 0.25 mg/kg once daily for patients greater than 2 years of age who weigh less than 20 kg OR c) 5 mg once daily for patients greater than 2 years of age who weigh more than 20 kg. Continuation - must meet initial criteria AND according to the prescriber, the patient has responded to Evrysdi and continues to have benefit from ongoing Evrysdi therapy by the most recent (within the past 4 months) objective measurement and/or assessment tool.</p>
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Ibrance	
PA Criteria	Criteria Details
Covered Uses	All-FDA approved indications not otherwise excluded. Liposarcoma.
Exclusion Criteria	
Required Medical Information	Diagnosis, hormone receptor status, concurrent therapies
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	3 years
Other Criteria	Breast Cancer - approve if pt has advanced or metastatic hormone receptor positive (HR+) [i.e., estrogen receptor positive (ER+) and/or progesterone receptor positive (PR+)] disease, and HER2-negative

	breast cancer when the pt meets ONE of the following: Pt is postmenopausal and Ibrance will be used in combination with anastrozole, exemestane, letrozole, or fulvestrant OR pt is premenopausal or perimenopausal and is receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) or has had surgical bilateral oophorectomy or ovarian irradiation AND Ibrance will be used in combination with anastrozole, exemestane, letrozole, or fulvestrant. Breast Cancer in Men - approve if pt has advanced or metastatic hormone receptor positive (HR+) [i.e., estrogen receptor positive (ER+) and/or progesterone receptor positive (PR+)] disease, and HER2-negative breast cancer and pt is receiving a gonadotropin-releasing hormone (GnRH) AND Ibrance will be used in combination with anastrozole, exemestane, letrozole, or fulvestrant. Lipsarcoma - Approve if pt patient has well-differentiated/dedifferentiated liposarcoma (WD-DDLS).
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Kalydeco	
PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	CF pts who are Homozygous for the phe508del (F508del) Mutation in the CFTR gene. CF pts with unknown CFTR gene mutation. Combination therapy with Orkambi, Symdeko, or Trikafta.
Required Medical Information	Diagnosis, specific CFTR gene mutations
Age Restrictions	4 months and older
Prescriber Restrictions	Must be prescribed by or in consultation with a pulmonologist or physician or specializes in the treatment of CF
Coverage Duration	3 years
Other Criteria	Cystic Fibrosis (CF) - Patient has at least ONE of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene: E56K, P67L, R74W, D110E, D110H, R117C, E193K, L206W, R347H, R352Q, A455E, D579G, S945L, S977F, F1052V, K1060T, A1067T, G1069R, R1070Q, R1070W, F1074L, D1152H, D1270N, G551D, G178R, S549N, S549R, G551S, G1244E, S1251N, S1255P, G1349D, 2789+5G—A, 3272-26A—G, 3849+10kbC-T, 711+3A-G, E831X, R117H, A120T, A234D, A349V, D192G, D924N, E882K, F311L, F311delF508C, F508C, S1251N, G178E, G194R, G314E, G576A, G970D, G1249R, H939R, H1375P, I148T, I175V, I807M, I1027T, I1139V, L320V, L967S, L997F, L1480P, M152V, M952I, M952T, Q237E, Q237H, Q359R, Q1291R, R75Q, R117G, R117L, R117P, R170H, R347L, R553Q, R668C, R792G, R933G, R1162L, R1283M, S589N, S737F, S1159F, S1159P, T338I, T1053I,

	V232D, V562I, V754M, V1293G, W1282R, Y1014C, or Y1032C.
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Kisqali	
PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Breast cancer in men.
Exclusion Criteria	
Required Medical Information	Diagnosis, hormone receptor status, concurrent therapies
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	3 years
Other Criteria	Breast Cancer - approve if pt has advanced or metastatic hormone receptor positive (HR+) [i.e., estrogen receptor positive (ER+) and/or progesterone receptor positive (PR+)]disease, and HER2-negative breast cancer when the pt meets ONE of the following: Pt is postmenopausal and Kisqali will be used in combination with anastrozole, exemestane, letrozole, or fulvestrant OR pt is premenopausal or perimenopausal and is receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) or has had surgical bilateral oophorectomy or ovarian irradiation AND Kisqali will be used in combination with anastrozole, exemestane, letrozole, or fulvestrant. Breast Cancer in Men - approve if pt has advanced or metastatic hormone receptor positive (HR+) [i.e., estrogen receptor positive (ER+) and/or progesterone receptor positive (PR+)]disease, and HER2-negative breast cancer and pt is receiving a gonadotropin-releasing hormone (GnRH) AND Kisqali will be used in combination with anastrozole, exemestane, letrozole, or fulvestrant.

Lynparza	
PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical	Diagnosis, mutation results, other therapies tried

Information	
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	3 years
Other Criteria	<p>Breast Cancer, Recurrent or Metastatic - approve if pt has germline BRCA mutation-positive recurrent or metastatic breast cancer and has human epidermal growth factor receptor 2 (HER2)-negative breast cancer. Ovarian Cancer – Treatment - approve if pt has a germline BRCA-mutation and has progressed on two or more prior lines of chemotherapy. Ovarian, Fallopian Tube, or Primary Peritoneal Cancer – Maintenance, Monotherapy - Approve if pt has a germline or somatic BRCA mutation-positive disease as confirmed by an approved test and is in complete or partial response to first-line platinum-based chemotherapy regimen OR pt is in complete or partial response after at least two platinum-based chemotherapy regimens. Ovarian, Fallopian Tube, or Primary Peritoneal Cancer – Maintenance, Combination Therapy - approve if being used in combination with bevacizumab AND pt has homologous recombination deficiency (HRD)-positive disease as confirmed by an approved test (which includes pts with BRCA mutation-positive disease) AND pt is in complete or partial response to first-line platinum-based chemotherapy regimen. Pancreatic Cancer – Maintenance Therapy - Patient has a germline BRCA mutation-positive metastatic disease and the disease has not progressed on at least 16 weeks of treatment with a first-line platinum-based chemotherapy regimen. Prostate Cancer - Approve if pt has metastatic castration resistant prostate cancer, the medication is used concurrently with a gonadotropin-releasing hormone (GnRH) analog or pt has had a bilateral orchiectomy, the pt has germline or somatic homologous recombination repair (HRR) gene-mutated disease (HRR gene mutations include BRCA1, BRCA2, ATM, BARD1, BRIP1, CDK12, CHEK1, CHEK2, FANCL, PALB2, RAD51B, RAD51C, RAD51D, or RAD54L), pt does not have a PPP2R2A mutation, and pt has been previously treated with at least one androgen receptor-directed therapy (e.g. abiraterone, Xtandi, Nubeqa, or Erleada). Breast Cancer, Adjuvant therapy - Approve if pt has germline BRCA mutation-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer, and meets one of the following: Pt has hormone receptor positive (HR+) [i.e., estrogen receptor positive {ER+} and/or progesterone receptor positive {PR+}] disease and did not have a pathologic complete response to neoadjuvant therapy or has node positive disease after receiving adjuvant therapy OR Pt has hormone receptor negative disease (HR-) and has tried neoadjuvant or adjuvant therapy and has residual disease. Uterine Leiomyosarcoma - Approve if pt has BRCA2-altered disease and has tried one systemic regimen.</p>

Lysosomal Storage Disease Enzyme Replacement Therapies	
PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Diagnosis, confirmatory testing results
Age Restrictions	Acid alpha-glucosidase deficiency (Pompe disease) - 8 years or older
Prescriber Restrictions	prescribed by or in consultation with a geneticist, endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders
Coverage Duration	1 year
Other Criteria	<p>Acid alpha-glucosidase deficiency (Pompe disease) - Approve if pt has a laboratory test demonstrating acid alpha-glucosidase (GAA) activity at less than 40% of the lab-specific normal mean value and had a second confirmatory GAA enzyme activity assay in a separate sample (from purified lymphocytes, fibroblast, or muscle) or by GAA gene sequencing, pt's forced vital capacity (FVC) is 30 percent to 79 percent of predicted value while in the sitting position with a postural drop in FVC of 10 percent or more from upright to supine position, pt has the ability to walk 40 meters on a six minute walk test (assistive devices permitted), and pt has muscle weakness in the lower extremities. Continuation - Approve if pt is ambulatory (assistive devices permitted) and not ventilator dependent.</p> <p>Fabry disease - Approve.</p> <p>Gaucher disease - Approve.</p> <p>Mucopolysaccharidosis Type I (Hurler Syndrome, Hurler-Scheie Syndrome, and Scheie Syndrome) - Approve if the diagnosis was established by a laboratory test demonstrating deficient α-L-iduronidase activity in leukocytes, fibroblasts, plasma, or serum OR a molecular genetic test demonstrating α-L-iduronidase gene mutation.</p> <p>Mucopolysaccharidosis Type II (Hunter Syndrome) - Approve if the diagnosis was established by a laboratory test demonstrating deficient iduronate-2-sulfatase activity in leukocytes, fibroblasts, serum, or plasma OR a molecular genetic test demonstrating iduronate-2-sulfatase gene mutation.</p> <p>Mucopolysaccharidosis Type IVA (Morquio A Syndrome) - Approve if the diagnosis was established by a laboratory test demonstrating deficient N-acetylgalactosamine-6-sulfatase activity in leukocytes or fibroblasts OR a molecular genetic test demonstrating N-acetylgalactosamine-6-sulfatase gene mutation.</p>

Rubraca	
PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Diagnosis, mutation results, previous therapies tried
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	3 years
Other Criteria	Ovarian, Fallopian Tube, or Primary Peritoneal Cancer - Treatment: Approve if pt has a BRCA-mutation (germline or somatic) as confirmed by an approved test and has progressed on two or more prior lines of chemotherapy. Maintenance: Approve if pt is in complete or partial response after at least two platinum-based chemotherapy regimens. Prostate Cancer - Approve if pt has castration resistant metastatic disease that is BRCA-mutation positive (germline and/or somatic) AND the medication is used concurrently with a gonadotropin-releasing hormone (GnRH) analog or pt has had a bilateral orchiectomy AND pt has been previously treated with at least one androgen receptor-directed therapy AND pt has been previously treated with at least one taxane-based chemotherapy or is not a candidate or is intolerant to taxane-based chemotherapy, according to the prescriber. Uterine Leiomyosarcoma - Approve if pt has BRCA2-altered disease and has tried one systemic regimen.

Tabrecta	
PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	3 years

Other Criteria	Non-Small Cell Lung Cancer (NSCLC) - Approve if the patient has metastatic disease and the patient has either high-level MET amplification or mesenchymal epithelial transition (MET) exon 14 skipping mutations as detected by an approved test.
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Talzenna	
PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Diagnosis, BRCA mutation status, HER2 status
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	3 years
Other Criteria	Breast Cancer - Approve if pt has recurrent or metastatic breast cancer which is germline BRCA mutation-positive and human epidermal growth factor receptor 2 (HER2)-negative.

Tepmetko	
PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Diagnosis, mutation results
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	3 years
Other Criteria	Non-Small Cell Lung Cancer (NSCLC) - Approve if the patient has metastatic disease and the patient has either high-level MET amplification or mesenchymal epithelial transition (MET) exon 14 skipping mutations as detected by an approved test.

Verzenio	
PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Diagnosis, hormone receptor status, concurrent therapies
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	Breast Cancer, Early - 2 years. Breast Cancer, Advanced or Metastatic - 3 years
Other Criteria	<p>Breast Cancer, Early - Approve if pt has hormone receptor positive (HR+) [i.e., estrogen receptor positive (ER+) and/or progesterone receptor positive (PR+)]disease, HER2-negative breast cancer, node-positive disease at high risk of recurrence (High risk includes patients with ≥ 4 positive lymph nodes, or 1-3 positive lymph nodes with one or more of the following: Grade 3 disease, tumor size greater than 5 cm, or a Ki-67 score of greater than 20%), and meets one of the following: 1) Verzenio will be used in combination with anastrozole, exemestane, or letrozole and pt is a postmenopausal woman, a pre/perimenopausal woman who is receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) agonist or has had surgical bilateral oophorectomy or ovarian irradiation, or is a man and is receiving a gonadotropin-releasing hormone (GnRH) analog OR 2) Verzenio will be used in combination with tamoxifen and pt is postmenopausal or is a pre/perimenopausal woman who is receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) agonist or has had surgical bilateral oophorectomy or ovarian irradiation. Breast Cancer, Recurrent or Metastatic in women - Approve if pt has hormone receptor positive (HR+) [i.e., estrogen receptor positive (ER+) and/or progesterone receptor positive (PR+)]disease, HER2-negative breast cancer, pt is postmenopausal or is a pre/perimenopausal woman who is receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) agonist or has had surgical bilateral oophorectomy or ovarian irradiation, and meets one of the following: 1) Verzenio will be used in combination with anastrozole, exemestane, letrozole, or fulvestrant OR 2) Verzenio will be used as monotherapy, the pt's breast cancer has progressed on at least one prior endocrine therapy, and the pt has tried chemotherapy for metastatic breast cancer. Breast Cancer in Men, Recurrent or Metastatic - Approve if pt has hormone receptor positive (HR+) [i.e., estrogen receptor positive (ER+) and/or progesterone receptor positive (PR+)]disease, HER2-negative breast cancer, and pt meets one of the following: 1)</p>

	Verzenio will be used in combination with anastrozole, exemestane, letrozole, or fulvestrant and pt is receiving a gonadotropin-releasing hormone (GnRH) analog OR 2) Verzenio will be used in combination with fulvestrant OR 3) Verzenio will be used as monotherapy, the pt's breast cancer has progressed on at least one prior endocrine therapy, and the pt has tried chemotherapy for metastatic breast cancer.
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Zokinvy	
PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	Progeroid Laminopathies. Other Progeroid Syndromes.
Required Medical Information	Diagnosis, test results
Age Restrictions	1 year and older
Prescriber Restrictions	Prescribed by or in consultation with a geneticist or pediatric cardiologist
Coverage Duration	1 year
Other Criteria	Hutchinson-Gilford Progeria Syndrome - Approve if the pt has a body surface area greater than or equal to 0.39 m ² and genetic testing demonstrates a confirmed pathogenic mutation in the LMNA gene consistent with Hutchinson-Gilford Progeria Syndrome.